COPY -Application Sumner Regional Medical center

CN1409-041

Sumner Regional Medical Center

Certificate of Need Application

To Initiate Positron Emission Tomography ("PET") Services at Sumner Station

September 15, 2014

1. Name of Facility, Agency, or Institution	10°) 10°)
Sumner Regional Medical Center (for its Sumner S	Station Campus)
Name	
225 Big Station Camp Road	Sumner
Street or Route	County
TN	
City	e Zip Code
2. Contact Person Available for Responses to Que	estions
Michael Herman	Chief Operating Officer
Name	Title
Sumner Regional Medical Center	Michael.Herman@LPNT.net
Company Name	Email address
555 Hartsville Pike Gallati	in TN 37066
Street or Route	City State Zip Code
	328-6695
Association with Owner Phone	e Number Fax Number
3. Owner of the Facility, Agency or Institution	
Sumner Regional Medical Center, LLC	615-72-8500
Name	Phone Number
330 Seven Springs Way	Sumner
Street or Route	County
BrentwoodTN	37027
City	e Zip Code
See <u>Attachment A, Item 3</u>	
4. Type of Ownership of Control (Check One)	
A. Sole Proprietorship F.	,
B. Partnership	Political Subdivision)
C. Lincite of Downsonship	
	Joint Venture Limited Liability Company X
	Limited Liability Company Other (Specify)

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5.	Name of Management/Operating Entity (If Applicable)									
	N/A									
	Name									
	Street or Route			<u>.</u>	County	_				
	City	-	St	ate	Zip Code					
	PUT ALL ATTACHMENTS AT T REFERENCE THE APPLICABLE I					AND				
6.	Legal Interest in the Site of the In-	<u>stitution</u>	(Ch	eck One)						
	A. OwnershipB. Option to PurchaseC. Lease of Years			Option to Lea Other (Specify						
	PUT ALL ATTACHMENTS AT TI REFERENCE THE APPLICABLE IT See <u>Attachment A, Item 6</u>					AND				
7	Type of Institution (Charless ann	ronrioto	mo	ro than ana ra	onanaa may anniy)					
7.	A. Hospital (Specify) acute care B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty C. ASTC, Single Specialty D. Home Health Agency E. Hospice F. Mental Health Hospital G. Intellectual Disability Institutional Habilitation Facility (IDIHF) (ICF/IID formerly (ICF/MR)	X	H. J. J. K. L. M. N.	Nursing Home Outpatient Dia Rehabilitation Residential Ho Nonresidentia Substitution-B Center for Op Birthing Center Other Outpatie	e agnostic Center Eacility Sospice I sased Treatment iate Addiction					
8.	Purpose of Review (Check as app A. New Institution B. Replacement/Existing Facility C. Modification/Existing Facility D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) Positron Emission Tomography E. Discontinuance of OB Services F. Acquisition of Equipment		G.	Change in Belle [Please note to by underlining response: Incorporation, Incorpora	d Complement he type of change the appropriate rease, Decrease, Distribution, Relocation]					

9,	Bed Complement Data Please indicate current and proposed distribution and certification of facility beds.								
			Current <u>Licensed</u>	Beds *CON	Staffed <u>Beds</u>	Beds <u>Proposed</u>	TOTAL Beds at <u>Completion</u>		
	A. Medical		90	0	90	0	90		
	B. Surgical								
	C. Long-Term Care Hospital								
	D. Obstetrical		15	0	15	0	15		
	E. ICU/CCU		18	O	18	00	18		
	F. Neonatal								
	G. Pediatric								
	H. Adult Psychiatric								
	 Geriatric Psychiatric 		12		12		12		
	J. Child/Adolescent Psychiatr	ic							
	K. Rehabilitation		20		20	-	20		
	L. Nursing Facility - SNF (Medi	care only)							
	M. Nursing Facility - NF (Medic	aid only)							
	N. Nursing Facility – SNF/NF (Medicaid/Medicare)	(dually certified							
	O. Nursing Facility – Licensed	(non-Certified)			-		:		
	P. IDIHF	(non ocranou)					-		
	Q. Adult Chemical Dependence	.v							
	R. Child and Adolescent Chen	•				-) (
	Dependency								
	S. Swing Beds						-		
	T. Mental Health Residential	Freatment					; ;		
	U. Residential Hospice				·				
	TOTAL		155	0	155	0	155		
	*CON-Beds approved but not yet in	n service		:1					
10.	Medicare Provider Number	1447571658	B						
	Certification Type	Acute Care	Hospital						
11.	Medicaid Provider Number	044-0003							
	Certification Type	Acute Care	Hospital						
40				or Madi	0040 006	Nor Modio	old?		
12.	If this is a new facility, will co	eruncation be	Sougniti	or wear	care and	I/Or Wealc	alur		
	Yes								
	No								
	X NA								
13.	Will this project involve the t	reatment of T	ennCare	particip	ants? <u>Y</u>	'es			

NOTE: Section B is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. Section C addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility, staffing, and how the project will contribute to the orderly development of adequate and effective healthcare.

Response:

Sumner Regional Medical Center ("SRMC") proposes to initiate Positron Emission Tomography ("PET") service at its existing outpatient campus, known as "Sumner Station," located on Big Station Camp Boulevard just off Vietnam Veterans Parkway, approximately 6.9 miles west of the main campus. PET services are currently not available in the community, and the availability of the service at Sumner Station will alleviate the travel burden on cancer patients who now must drive to Nashville for PET scans.

SRMC is a 155-bed acute care hospital in Gallatin, TN. It is part of LifePoint Hospitals. LifePoint Hospitals is headquartered in Brentwood, TN. It operates 63 hospitals in 20 states, including 10 in Tennessee. SRMC is one of 15 LifePoint hospitals that was recognized by the Joint Commission in 2013 as a <u>Top Performer in Key Quality Measures</u>.

The Sumner Station campus of SRMC was constructed in 2007, and it is a two story building with approximately 95,998 sq. ft. of space. Approximately 11,757 sq. ft. are currently used for outpatient imaging (CT, MRI, ultrasound, mammography and x-ray), and approximately 9,900 sq. ft. are used for outpatient rehabilitation (physical therapy, occupational therapy and speech therapy) and a sports medicine physician. The remaining space will be developed to support the health care needs of the community, including the proposed relocation of radiation therapy and the installation of a PET/CT unit that is the subject of this application.

SRMC's primary service area for radiation therapy is Sumner and Macon Counties, and SRMC believes that its primary service area for PET service will be the same.

The need for the project is based on the lack of PET services in the area. Most patients in the region who need PET scans currently obtain the service in Nashville, approximately 30 miles from Gallatin. The availability of PET services at Sumner Station will alleviate the travel burden on cancer patients. The need for PET services in community is further

supported by the fact that the cancer incidence rates in Sumner and Macon counties are higher than the statewide average. Based on information in the report titled <u>Cancer in Tennessee 2005-2009</u> published in 2013 by the Division of Policy, Planning and Assessment, Tennessee Department of Health, the following information is relevant:

- For the period 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate.
- Tennessee's cancer incidence rate for the period was 476.8 per 100,000.
- Sumner County's cancer incidence rate for the period was 487.6 per 100,000, 2.3% higher than the Tennessee rate
- Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee rate.

Given that cancer occurs with more frequently in the service area than the statewide average, it is important that state of the art cancer diagnostic resources by conveniently available. SRMC is committed to continue the modernization and enhancement of its cancer diagnosis and treatment capabilities, as evidenced by this application for PET services. Mammography and CT imaging services are already provided at Sumner Station.

SRMC's cancer service has been accredited by the American College of Surgeons. In addition to radiation therapy and diagnostic services, SRMC provides an array of cancer support services including community education, pastoral care and nutrition services. Patient support groups are available through a partnership with Gilda's Club. Chemotherapy is provided in the community by Tennessee Oncology, the largest oncology group in the region, which participates in clinical trials through the Sarah C Cannon Center Cannon Center.

The number and types of physicians on staff at SRMC involved in cancer care are as follows:

- Radiation oncologist 1 active staff; 10 coverage staff
- Medical oncologist 2 active staff; 16 consulting/coverage staff
- General Surgeons 4 active staff
- Urologists 4 active staff
- Radiologists 9 active staff
- Pathologists 4 active staff

The PET service proposed by SRMC will be used for cancer diagnosis and treatment planning only. There are no current plans to provide PET scans for neurological or cardiac patients. The availability of PET at Sumner Station will complement other cancer services in the community, including radiation therapy, chemotherapy and surgery services.

The project will require renovation and build-out of approximately 1,425 sq. ft. of shelled space in an existing building for the scan room and support areas. The PET service will be provided by a G.E. Discovery PET/CT Imaging System, which utilizes integrated PET and CT functionality, a feature that has become the standard for PET services. The total project cost, including the PET/CT unit and maintenance for 5 years is approximately \$2,687,896, which will be funded by a capital contribution from the applicant's parent, LifePoint Hospitals. The only staff required for the project is one (1) nuclear medicine technologist FTE.

- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.
 - A. For the establishment or modification of a healthcare institution describe the development of and need for the proposal. Health care institutions include:
 - 1. Nursing home
 - 2. Hospital
 - 3. Ambulatory Surgical Treatment Center
 - 4. Birthing Center
 - 5. Mental Health Hospital
 - 6. Intellectual Disability Institutional Habilitation Facility
 - 7. Home Care Organization (Home Health Agency or Hospice Agency)
 - 8. Outpatient Diagnostic Center
 - 9. Rehabilitation Facility
 - 10. Residential Hospice
 - 11. Nonresidential Substitution-based Treatment Center for Opiate Addition

Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applications with construction, modification and/or renovation costs should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

<u>Response</u>: The project will require approximately 1,425 sq. ft. of interior renovation for the scan room and support areas.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Response: Not applicable.

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART

Proposed Final Cost / SF	New Total	\$455,990			· · · · · · · · · · · · · · · · · · ·											
	Renovated	\$322.80							Sad Company							
d)	Total	1,425														
Proposed Final Square Footage	New													populou	ווכוממפת	Included
Pro Squ	Renovated	1,425												Included		Included
Proposed Final	Location	Sumner Station										16				
Temporary	Location	1														
Existing																
Existing	Location															
A. Unit / Department													B. Unit/Depart. GSF Sub-Total	C. Mechanical/ Electrical GSF		D. Circulation

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):
 - 1. Adult Psychiatric Services
 - 2. Hospital-Based Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
 - 3. Burn Units
 - 4. Cardiac Catheterization Services
 - 5. Child and Adolescent Psychiatric Services
 - 6. Extracorporeal Lithotripsy
 - 7. Home Health Services
 - 8. Hospice Services
 - 9. Magnetic Resonance Imaging (MRI)
 - 10. Neonatal Intensive Care Unit
 - 11. Opiate Addiction Treatment provided through a Non-Residential Substitution-Based Treatment Center for Opiate Addiction
 - 12. Open Heart Surgery
 - 13. Positron Emission Tomography
 - 14. Radiation Therapy/Linear Accelerator
 - 15. Rehabilitation Services
 - 16. Swing Beds
 - 17. Discontinuation of any obstetrical or maternity service
 - 18. Closure of a Critical Access Hospital
 - 19. Elimination in a critical access hospital of any service for which a certificate of need is required

Response: The need for this project is based on current unavailability of PET services in the region. Cancer patients located in the service area must now travel 30 miles or more to Nashville for PET scans that are essential to cancer diagnosis and treatment planning. Many cancer patients are elderly or otherwise frail, and the project will alleviate the travel burden these and other cancer patients now face.

D. Describe the need to change location or replace an existing facility.

Response: Not applicable.

- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$2.0 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:
 - 1. For major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 - 1. Brief description of equipment including characteristics such as fixed or mobile; expected vendor and model (if known); for MRI use descriptors such as Tesla strength, open/closed bore; for linear accelerators use descriptors such as MeV strength, IMRT/IGRT/SRS capability; etc.;
 - 2. Total cost (As defined by Agency Rule 0720-9-.01(13))
 - a. By Purchase or

- b. By Lease;
- 3. Expected useful life;
- 4. List of clinical applications to be provided;
- 5. Documentation of FDA approval; and
- 6. For mobile major medical equipment list all sites that the unit is currently serving and its current schedule of operations at those sites.

<u>Response</u>: The proposed PET/CT unit is a GE Discovery PET/CT Imaging System. The unit will be purchased, and the total cost of the unit including maintenance for 5 years is \$1,498,728. The unit will be used for cancer diagnosis and treatment planning and evaluation. A copy of the FDA approval is at <u>Attachment B. II, E.,1</u>.

b. Provide current and proposed schedules of operations.

<u>Response</u>: The hours and days of operation of the proposed PET service will be 8:00-4:30.

Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment.

<u>Response</u>: The PET/CT unit will be purchased. The vendor quote is attached under Attachment B.II, E., 2.

- III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:
 - 1. Size of site (in acres);
 - 2. Location of structure on the site; and
 - 3. Location of the proposed construction.
 - 4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for <u>all</u> projects.

Response: Plot plan attached under Attachment B, III. (A).

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients. (Not applicable to home health or hospice agency applications.)

<u>Response</u>: Sumner Station is located on Big Station Camp Boulevard, in between Long Hollow Pike and Vietnam Veterans Bypass. There is not direct bus service to the facility, but Sumner Station is easily accessible by car. Additionally, Mid-Cumberland Human Resources Agency RTS Public Transit serves the area.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an

8 1/2" x 11" sheet of white paper. (Not applicable to home health or hospice agency applications.)

NOTE: **<u>DO NOT SUBMIT BLUEPRINTS</u>**. Simple line drawings should be submitted and need not be drawn to scale.

Response: The floor plan is attached as Attachment B,IV.

- V. For a Home Health Agency or Hospice, identify:
 - 1. Existing service area by County;
 - 2. Proposed service area by County;
 - 3. A parent or primary service provider;
 - 4. Existing branches; and
 - 5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

- 1. Describe the relationship of this proposal toward the implementation of the State Health Plan and <u>Tennessee's Health: Guidelines for Growth</u>, if applicable.
 - a. Please discuss how the proposed project will relate to the <u>5 Principles for Achieving</u>
 <u>Better Health</u> found in the State Health Plan. Please list each principle and follow it with a response.

Response:

- 1. The purpose of the State Health Plan is to improve the health of Tennesseans.
 - a. How will this proposal protect, promote, and improve the health of Tennesseans over time?

- b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?
- c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

Response: PET service is an important tool for the diagnosis and treatment of cancer. It is not currently available in the community. This project will facilitate the diagnosis and treatment of cancer making state-of-the-art imaging available at a convenient location that will be more accessible than the existing service. The project will also reduce the stress on sick patients by making it easier to access care.

- 2. Every citizen should have reasonable access to health care.
 - a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.
 - b. How will this proposal improve information provided to patients and referring physicians?
 - c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

Response: The PET service will be available to all patients. SRMC is contracted with all existing TennCare MCOs in the area, and SRMC intends to continue its participation in all TennCare MCOs when the new MCO contracts are implemented in 2015.

- 3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.
 - a. How will this proposal lower the cost of health care?
 - b. How will this proposal encourage economic efficiencies?
 - c. What information will be made available to the community that will encourage a competitive market for health care services?

<u>Response</u>: This project achieves economic efficiency because it makes use of an existing building on an existing outpatient campus in order to provide the benefits of enhanced convenience and accessibility for advance imaging technology for cancer patients. The project will require only minimal additional staffing.

- 4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
 - a. How will this proposal help health care providers adhere to professional standards?

b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

<u>Response</u>: The project contributes to quality of care by making state-of-the-art imaging for cancer patients more accessible, thus increasing the possibility of early diagnosis and enhancing treatment planning. SMRC's commitment to quality care is evidenced by its designation by the Joint Commission as a <u>Top</u> <u>Performer in Key Quality Measures</u>.

- 5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.
 - a. How will this proposal provide employment opportunities for the health care workforce?
 - b. How will this proposal complement the existing Service Area workforce?

<u>Response</u>: This project will require only 1 nuclear medicine technologist FTE, and thus will not have a material effect on the health care workforce.

b. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9 of the <u>Guidelines for Growth</u>) here.

Response: The PET criteria in the State Health Plan are addressed as follows:

PET Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

Response: SRMC does not project volumes that will achieve the minimums in this criterion. SRMC notes, however, that there is a need for the service in the area, and the project is financially viable. Most patients in the region who need PET scans currently obtain the service in Nashville, approximately 30 miles from Gallatin. The availability of PET services at Sumner Station will alleviate the travel burden on cancer patients. The need for PET services in community is further supported by the fact that the cancer incidence rates in Sumner and Macon counties are higher than the statewide average. Based on information in the report titled Cancer in

Tennessee 2005-2009 published in 2013 by the Division of Policy, Planning and Assessment, Tennessee Department of Health, the following information is relevant:

- For the period 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate.
- Tennessee's cancer incidence rate for the period was 476.8 per 100,000.
- Sumner County's cancer incidence rate for the period was 487.6 per 100,000, 2.3% higher than the Tennessee rate
- Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee rate.

Given that cancer occurs with more frequently in the service area than the statewide average, it is important that state of the art cancer diagnostic resources by conveniently available.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

Response: Not applicable.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

<u>Response</u>: The proposal is cost-effective, because it makes use of an existing building on an existing outpatient campus. A part-time mobile unit was determined not to be advantageous, because the part-time availability would compromise availability and convenience.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Response: Not applicable.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures/day x 50 days/year = 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

Response: Not applicable. The proposed unit is the first PET unit in the service area.

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

Response: FDA approval is documented at Attachment B.II. E. 1.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

<u>Response</u>: The applicant will comply with all applicable standards. See <u>Attachment C., Economic Feasibility -1</u>. In addition, the PET facility will be operated under the same radiation safety standards set forth in SRMC's radiation safety manual.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

<u>Response</u>: The PET center will be licensed and operated as part of SRMC and thus subject to the same emergency management plan and procedures that otherwise apply SRMC. A patient at the PET center who has a medical emergency will be transported by ambulance to SRMC.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

<u>Response</u>: Physicians who refer patients to SRMC for PET procedures will have no financial interest in SRMC or the PET, and PET procedures will be performed on only those patients for whom PET is determined to be medically necessary in the independent medical judgment of the referring physicians. In addition, SRMC has developed draft protocols, a copy of which is attached at <u>Attachment C.</u>, Need – PET Standards, item 6.d.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board

of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

<u>Response</u>: The PET service will be under the medical direction of Dr. Glen Nabors, a board certified radiologist with Sumner Radiology, PC. Other radiologists in Sumner Radiology are also qualified to interpret PET scans. The CVs of Dr. Nabors and the other physicians who will interpret PET scans are attached at Attachment C, Need-PET Standards, item 6.e.

SRMC already has applicable radiological permits from the Division of necessary for existing CT services. SRMC has made preliminary inquiry at the Division regarding a radioactive materials license for the PET at the Sumner Station campus, and it is confident that it will have no difficulty obtaining the appropriate license for the PET unit.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

<u>Response</u>: The proposed PET will be operated by SRMC as part of the hospital, and Dr. Nabors is an active member of SRMC's staff.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: SRMC will submit file its equipment registry reports timely.

- 8. In light of Rule 0720-4-.01(1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
 - c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or
 - d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

<u>Response:</u> SRMC believes it should receive special consideration under this criterion for several reasons:

- SRMC has long history as a participating provider in the TennCare program and contracting with all MCOs serving the region.
- As previously noted, the incidence of cancer in Sumner and Macon counties is higher than the statewide average. The incidence rate in Sumner County is 2.3% higher than the statewide rate and the incidence rate in Macon County is 16% higher than the statewide rate. These higher incidence rates emphasize the need for better access in the community to cancer diagnosis and treatment capabilities.
- All of Macon County and part of Sumner County are designated as medically underserved by the United States Health Resources and Administration.
- PET service does not exist in the area, and the project is financially viable.
- c. Applications that include a Change of Site for a proposed new health care institution (one having an outstanding and unimplemented CON), provide a response to General Criterion and Standards (4)(a-c) of the <u>Guidelines for Growth</u>.

Response: Not applicable.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

<u>Response</u>: SRMC's long-range plan includes the intention to maintain and upgrade services and technology to meet community expectations for modern health care. This project is consistent with this plan because it will bring to the community state-of-the-art imaging for the diagnosis and treatment of cancer.

3. Identify the proposed service area <u>and</u> justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

<u>Response</u>: SRMC's believes its primary service area for PET service will be the same as its service area for its existing radiation therapy, specifically Sumner and Macon counties. From 2010-2012, approximately 84% of SRMC's radiation therapy patients came from these two counties. SRMC expects a similar proportion of its PET patients will come from these counties. A map showing the service area is attached as Attachment C., Need - 3.

4. A. 1) Describe the demographics of the population to be served by this proposal.

Response: See demographic information at Attachment C. Need – 4.A.(1).

2) Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area:

Demographic Variable/ Geographic Area	Sumner County	Macon County	Service Area Total	State of TN Total
Total Population – Current Year 2014	172,282	23,188	195,470	6,588,698
Total Population – Projected Year 2016	177,876	23,654	201,530	6,740,579
Total Population - % change	3.25%	2%	3.1%	2.3%
*Target Population – Current Year	25,164	3,647	28,811	981,984
*Target Population – Projected Year	27,389	3,896	31,285	1,069,460
Target Population - % Change	8.8%	6.8%	8.6%	8.9%
Target Population – Projected Year as % of Total	15.4%	16.5%	15.5%	15.9%
Median Age	38.7	38.3		38
Median Household Income	\$55,560	\$35,452		\$44,140
TennCare Enrollees	24,135	6,061	30,196	1,241,028
TennCare Enrollees as % of Total	14%	26%	15.4%	18.8%
Persons Below Poverty Level	16,260	5,295	21,555	1,129,610
Persons Below Poverty Level as % of Total	9.8%	23.5%	11.4%	17.3%

^{*}Target Population is 65+ per application instructions. Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics; TennCare Bureau; U.S. Census Bureau.

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

<u>Response</u>: SRMC is contracted with all TennCare MCOs and the new facility will thus be available to all TennCare patients. Cancer disproportionately affects elderly patients, and cancer patients in the region must travel to Nashville in order to get a PET scan. The PET service proposed by SRMC will make the technology more accessible to all patients in the service area.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. Projects including surgery should report the number of cases and the average number of procedures per case.

<u>Response</u>: There are no approved but unimplemented CONs in the service area for PET service.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization through the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

Response:

	2011	2012	2013	Year 1	Year 2
SRMC				241	337

SRMC currently operates the only radiation therapy service in Sumner and Macon counties. Approximately, 90% of SRMC's radiation therapy volume is from Sumner and Macon counties, and SRMC has approximately 49% of the radiation therapy market from Sumner and Macon counties. The Applicant assumes that its patient origin and market share for PET will be similar to its radiation therapy patient origin and market share. Based on information from the Agency's equipment registry provided by Alecia Craig, the residents of Sumner and Macon counties in the period 2011-2013 received an average of 620 PET scans per year. For its PET service, SRMC assumes in year 1 it will serve 35% of the PET patients from Sumner and Macon counties and these patients will be 90% of its total PET volume for the year, and in year 2 it will serve 49% of the PET patients from Sumner and Macon counties and these patients will be 90% of total PET volumes. The projections set forth above are based on these assumptions.

ECONOMIC FEASIBILITY

- 1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
 - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
 - The cost for fixed and moveable equipment includes, but is not necessarily limited
 to, maintenance agreements covering the expected useful life of the equipment;
 federal, state, and local taxes and other government assessments; and installation
 charges, excluding capital expenditures for physical plant renovation or in-wall
 shielding, which should be included under construction costs or incorporated in a
 facility lease.
 - For projects that include new construction, modification, and/or renovation; <u>documentation must be</u> provided from a licensed architect or construction professional that support the estimated construction costs. Please provide a letter that includes:
 - a general description of the project;

- 2) estimate of the cost to construct the project to provide a physical environment, according to applicable federal, state and local construction codes, standards, specifications, and requirements; and
- 3) attesting that the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the most recent AIA Guidelines for Design and Construction of Hospital and Health Care Facilities.

Response: Architect letter attached at Attachment C., Economic Feasibility - 1.

PROJECT COSTS CHART

A.	Const	ruction and equipment acquired by purchase:		[], [], [],
	1.	Architectural and Engineering Fees		\$75,000
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees		\$47,000
	3.	Acquisition of Site		
	4.	Preparation of Site		
	5.	Construction Costs		\$460,000
	6.	Contingency Fund		\$115,000
	7.	Fixed Equipment (Not included in Construction Contract)		\$1,498,728
	8.	Moveable Equipment (List all equipment over \$50,000)		\$486,134 (no items over \$50,000)
	9.	Other (Specify)		
В.	Acqui	sition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)		
	2.	Building only		
	3.	Land only		
	4.	Equipment (Specify)		
	5.	Other (Specify)		
C.	Finan	cing Costs and Fees:		
	1.	Interim Financing		
	2.	Underwriting Costs		
	3.	Reserve for One Year's Debt Service		·
	4.	Other (Specify)		
D.	Estim (A+B-	ated Project Cost +C)		\$2,681,862
E.	CON	Filing Fee		\$6,034
F _k		Estimated Project Cost		
	(D+E)		TOTAL	\$2,687,896

	financ appli	e check the applicable item(s) below and briefly summarize how the project will be sed. (Documentation for the type of funding MUST be inserted at the end of the cation, in the correct alpha/numeric order and identified as Attachment C, omic Feasibility-2.)
	A.	Commercial loanLetter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
	B.	Tax-exempt bondsCopy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
	C.	General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
	D.	GrantsNotification of intent form for grant application or notice of grant award; or
\boxtimes	E.	Cash ReservesAppropriate documentation from Chief Financial Officer.
	F.	Other—Identify and document funding from all other sources.

Response: Funding confirmation attached at Attachment C, Economic Feasibility -2.

Identify the funding sources for this project.

2.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

<u>Response</u>: According to the HSDA's website, the 2011-2013 construction costs for hospitals in the 3rd quartile were \$249.00 per sq. ft. for renovation. The construction costs for the project are projected to be \$322.80 per sq. ft. for renovation, which is reasonable as confirmed by the project architect.

4. Complete Historical and Projected Data Charts on the following two pages--<u>Do not modify</u> the <u>Charts provided or submit Chart substitutions!</u> Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the **Proposal Only** (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology, legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

<u>Response</u>: Average gross charge per treatment is \$7,500, average deduction will be \$5,595 and average net charge will be \$1,905.

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in <u>January</u> (Month).

Ü			Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
A.	Utiliz	zation Data (Adjusted Admissions)	14,330	15,146	15,967
B.	Rev	enue from Services to Patients			
	1.	Inpatient Services	\$ <u>152,840,000</u>	\$ <u>182,454,000</u>	\$227,555,000
	2.	Outpatient Services	<u>165,289,000</u>	200,447,000	226,454,000
	3.	Emergency Services	<u>34,577,000</u>	42,615,000	54,042,000
	4.	Other Operating Revenue	2,316,000	2,186,000	1,090,000
		(Specify)	*****	*407 700 000	¢ E00 444 000
_		Gross Operating Revenue	\$ <u>355,022,000</u>	\$ <u>427,702,000</u>	\$ <u>509,141,000</u>
C.		uctions from Gross Operating Revenue	*****	*****	#859 997 999
	1.:	Contractual Adjustments	\$273,125,000	\$288,553,000	\$353,807,000
	2.	Provision for Charity Care	8,248,000	8,372,000	9,247,000
	3.	Provisions for Bad Debt	14,369,000	<u> 18,874,000</u>	24,814,000
		Total Deductions	\$ <u>245,742,000</u>	\$ <u>315,799,000</u>	\$387,860,000
		RATING REVENUE	\$ <u>109,280,000</u>	\$ <u>111,903,000</u>	\$ <u>121,273,000</u>
D.	Ope	rating Expenses	vi		
	1.	Salaries and Wages	\$ <u>50,873,000</u>	\$ <u>50,953,000</u>	\$ 54,846,000
	2.	Physician's Salaries and Wages		le 	Sensone area
	3.	Supplies	<u>16,459,000</u>	17,051,000	17,517,000
	4.	Taxes	6,993,000	6,852,000	9,743,000
	5.	Depreciation	9,411,000	9,691,000	8,501,000
	6.	Rent	<u>826,000</u>	521,000	618,000
	7.	Interest, other than Capital		;(
	8.	Management Fees:			
		a. Fees to Affiliates	3,741,000	4,089,000	4,408,000
		b. Fees to Non-Affiliates		(()
	9.	Other Expenses – Specify on Page 23	<u> 15,961,000</u>	18,608,000	<u>19,353,000</u>
		Total Operating Expenses	\$ <u>104,264,000</u>	\$ <u>107,766,000</u>	\$ <u>114,985,000</u>
E.	Othe	er Revenue (Expenses) – Net (Specify)	\$	\$	\$
NET	OPE	RATING INCOME (LOSS)	\$ <u>5,016,000</u>	\$ <u>4,138,000</u>	\$ 6,288,000
F.	Сар	ital Expenditures			
	1.	Retirement of Principal	\$	\$	\$
	2.	Interest		-	
		Total Capital Expenditures	\$	\$	\$
		RATING INCOME (LOSS) PITAL EXPENDITURES	\$ <u>5,016,000</u>	\$ <u>4,138,000</u>	\$ <u>6,288,000</u>

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in <u>January</u> (Month).

				Year <u>2016</u>	Year <u>2017</u>
Α.		zation Data (PET Scans)		241	337
B.		enue from Services to Patients			Ф
	1.	Inpatient Services		4 000 000	\$
	2.	Outpatient Services		1,808,000	2,528,000
	3.	Emergency Services		>	
	4.	Other Operating Revenue (Specify)		. 4 900 000	£ 2.529.000
_	Dad		Gross Operating Revenue	\$ <u>1,808,000</u>	\$ <u>2,528,000</u>
C,		uctions from Gross Operating Reven	lue	\$ <u>1,245,000</u>	¢ 1.741.000
	1.	Contractual Adjustments		38,000	\$ <u>1,741,000</u> 54,000
	2.	Provision for Charity Care			91,000
	3.	Provisions for Bad Debt	Total Deductions	65,000 \$ 1,348,000	\$ <u>1,886,000</u>
NET	ODE	RATING REVENUE	Total Deductions	\$ <u>1,348,000</u> \$ <u>459,000</u>	\$ 642,000
D.	-			ф <u>459,000</u>	\$ <u>042,000</u>
D.	Оре 1.	rating Expenses Salaries and Wages		\$ 54,000	\$ 54,000
	2.	Physician's Salaries and Wages		Ψ	Ψ 34,000
	3.	•		75,000	121,000
	3. 4.	Supplies Taxes		11,000	42,000
	4 . 5.	Depreciation		259,000	259,000
	5. 6.	Rent		233,000	233,000
	6. 7.			1	-
	7. 8.	Interest, other than Capital			(
	Ο.	Management Fees a. Fees to Affiliates			
		b. Fees to Non-Affiliates			
	9.	Other Expenses – Specify on Page	23	42,000	101,000
	Э.		Total Operating Expenses	\$ <u>441,000</u>	\$ 577,000
E.	Othe	er Revenue (Expenses) – Net (Specit		\$	\$
		RATING INCOME (LOSS)	37	\$ 18,000	\$65,000
F.		ital Expenditures			¥ <u>33,333</u>
١.	1.	Retirement of Principal		\$	\$
	2.	Interest		T ₂	ST.)————————————————————————————————————
	۷.		Total Capital Expenditures	\$	\$
		RATING INCOME (LOSS) PITAL EXPENDITURES	The sale in my ballaland	\$ <u>18,000</u>	\$ <u>65,000</u>
_					

HISTORAL DATA CHART – OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
1. Professional Fees	\$ 2,582,000	\$ 2,628,000	\$_3,510,000
2. Contract Services	5,233,000	5,651,000	5,791,000
3. Repairs and Maintenance	3,531,000	3,527,000	3,890,000
4. Utilities	2,690,000	2,676,000	2,743,000
5. Insurance	(157,000)	886,000	692,000
6. Investment Income	(89,000)	R	
7. Other (Marketing, Recruiting, etc.)	2,171,000	3,240,000	2,727,000
Total Other Expenses	\$ <u>15,961,000</u>	\$ <u>18,608,000</u>	\$ <u>19,353,000</u>

PROJECTED DATA CHART – OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year <u>2017</u>	Year <u>2018</u>
1. Professional Fees	\$	\$
2. Contract Services		
3. Repairs and Maintenance		59,000
4. Utilities	12,000	12,000
5. Marketing, recruiting, etc.	30,00	30,000
6.		3
7.	·	
Total Other Expenses	\$42,000	\$101,000

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

<u>Response</u>: The average gross charge for PET scans will be \$7,500 per scan. This is a new service for SRMC, so it will not impact existing patient charges.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

<u>Response</u>: Based on 2013 information from the Health Services and Development Agency's Equipment Registry, SRMC's proposed charge will be slightly over the 3rd Quartile for the state, which is \$7,307.21. The median charge from the Equipment Registry is \$4,834.25. A comparison of SRMC's proposed charge and the Medicare allowable by procedure follows:

CPT	Description	SRM Change	Medicare Allowable
78811	PET, 1H area	\$7,500	\$1,056.12
78812	PET, skull-thigh	\$7,500	\$1,056.12
78813	PET, full body	\$7,500	\$1,056.12
78814	PET, w/ct ltd	\$7,500	\$1,056.12
78815	PET, w/ct skull-thigh	\$7,500	\$1,056.12
78816	PET, w/ct full body	\$7,500	\$1,056.12

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness; how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

<u>Response</u>: As indicated in the Projected Data Chart, the project will achieve positive financial results in the first year.

8. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

<u>Response</u>: SRMC is contracted with all TennCare MCOs that serve the region, and it is committed to do so in the future. Gross revenues from TennCare in year 1 are projected to be \$120,000 (6.63%) and gross revenues from Medicare are projected to be \$816,000 (45.13%).

9. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end

of the application, in the correct alpha-numeric order and labeled as <u>Attachment C, Economic Feasibility-9</u>.

<u>Response</u>: SRMC does have an audited financial statement, but it's 2013 unaudited balance sheet and income statement are attached under <u>Attachment C, Economic Feasibility - 9</u>.

- 11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:
 - a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

<u>Response</u>: Since SRMC already owns the building at Sumner Station, and in light of the outpatient services and medical offices that are on site at Sumner Station, SRMC did not consider alternative sites. Any other site would have been substantially more expensive because of the need to purchase land and construct a building or the need to lease space.

Another alternative would have been to contract with a mobile service on a part-time basis. SRMC determined that investing in a fixed PET unit as the superior alternative, because the fixed unit provides maximum availability and flexibility for patients and the fixed service achieves a positive financial result.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

<u>Response</u>: This project does not involve new construction, but makes cost-effective use of an existing building.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

<u>Response</u>: Lists of managed care contracts and provider contracts are attached under <u>Attachment C, Contribution to the Orderly Development of Health Care – 1</u>.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: This project will have only positive effects, because of improved patient convenience. In addition, SRMC believes the presence of PET service in the community will enhance the confidence of Sumner and Macon county residents that they can receive first-class treatment in their community rather traveling to Nashville. PET service does not currently exist in the market, so the project will not affect any other provider in the service

area. The patient benefits from PET services being available at Sumner Station are confirmed by the letter of support from Tennessee Oncology attached at <u>Attachment C., Orderly</u> Development of Health Care – 2.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: The PET service will require only 1 nuclear medicine technologist FTE:

<u>Position</u>	<u>FTE</u>	<u>Salary</u>
Nuclear Medicine Technologist	1	\$54,000

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities licensing requirements.

<u>Response</u>: The PET service will require only 1 addition to clinical staff. SRMC foresees no difficulty in filling this position.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review *policies and programs, record keeping, and staff education.*

<u>Response</u>: SRMC has reviewed and understands licensing and certification requirements applicable to its medical and clinical staff.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

<u>Response</u>: SRMC has an agreement with Austin Peay University, under which SRMC is a clinical training site for radiation therapy technologists. The Sumner Station campus is covered by this agreement.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Substance Abuse Services, the Department of Intellectual and Developmental Disabilities, and/or any applicable Medicare requirements.

<u>Response</u>: SRMC has viewed and understands the licensing requirements of the Department of Health.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure: Tennessee Department of Health

- Accreditation: Joint Commission. SRMC's cancer program is accredited by the American College of Surgeons Commission on Cancer Care.
- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.
 - <u>Response</u>: SRMC is accredited by the Joint Commission and its cancer program is accredited by the American College of Surgeons Commission on Cancer Care. A copy of SRMC's license from the Tennessee Department of Health and Joint Commission accreditation are attached under <u>Attachment C, Contribution to the Orderly Development of Health Care 7(c)</u>.
- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction. Please also discuss what measures the applicant has or will put in place to avoid being cited for similar deficiencies in the future.
 - <u>Response</u>: A copy of SRMCs' most recent survey and the plan of correction relative to the survey is attached under <u>Attachment C., Contribution to the Orderly Development of Health Care -7(d).</u>
- 8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.
 - Response: There are no judgments or orders to be reported in response to this item.
- 9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.
 - Response: There are no judgments to be reported in response to this item.
- 10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.
 - <u>Response</u>: SRMC will provide to the Health Services and Development Agency the information described in this item.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Response: Proof of Publication Attached.

NOTIFICATION REQUIREMENTS

(Applies only to Nonresidential Substitution-Based Treatment Centers for Opiate Addiction)

Please note that Tennessee Code Annotated 68-11-1607(c)(3) states that "...Within ten (10) days of filing an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the member of the House of Representatives and the Senator of the General Assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution based treatment center for opiate addiction has been filed with the agency by the applicant."

Please provide this documentation.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filling fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

Newspaper:

THE TENNESSEAN

Affidavit of Publications

State Of Tennessee Account Number: 540358 Advertiser: BUTLER, SNOW, O'MARA, STEVENS	TEAR SHEET ATTACHED
RE: Sumner Regional Medical Center - CERTIFI	
I, Sales Assistant for	or the
above mentioned newspaper, hereby certify that the attach	ed
advertisement appeared in said newspaper on the following	
Subscribed and sworn to me this	2014
NOTARY PUBLIC STATE OF TENNESSEE NOTARY PUBLIC OMNISSION EXPINES	

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center, a hospital owned by: Sumner Regional Medical Center, LLC with an ownership type of

limited liability company intends to file an application for a Certificate of Need to initiate positron emission tomography ("PET") service at its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, Tennessee. The project will require build-out of approximately 1,425 square feet of existing space and the purchase of G.E. Discovery PET/CT Imaging System. The total project cost is approximately \$2,687,896. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except positron emission tomography.

The anticipated date of filing the applica-September 15, 20 14 tion is:

The contact person for this project is Dan Elrod, Attorney, who may be reached at: Butler Snow LLP, 150 3rd Avenue South, Suite 1600, Nashville, TN 37201 615 / 651-6702

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency Andrew Jackson Building, 9th floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is critically scheduled. cation is originally scheduled; and (B)
Any other person wishing to oppose the
application must file written objection
with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

- 1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- 2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

Form HF0004 Revised 08/01/2012 Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. §68-11-1609(c): Nov. 2014

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

		DAYS	Anticipated Date
Phase		REQUIRED	(MONTH/YEAR)
1.	Architectural and engineering contract signed		Dec. 2014
2.	Construction documents approved by the Tennessee Department of Health	90	April. 2015
3.	Construction contract signed	90	April 2015
4.	Building permit secured	120	May 2015
5.	Site preparation completed	N/A	N/A
6.	Building construction commenced	145	May 2015
7.	Construction 40% complete	210	July 2015
8.	Construction 80% complete	270	Sept. 2015
9.	Construction 100% complete (approved for occupancy)	330	Nov. 2015
10.	*Issuance of license	330	Nov. 2015
11.	*Initiation of service	345	Dec. 2015
12.	Final Architectural Certification of Payment	345	Dec. 2015
13.	Final Project Report Form (HF0055)	420	Feb. 2016

^{*} For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF <u>Tennessee</u>
COUNTY OF <u>Davidson</u>
Dan H. Elvod , being first duly sworn, says that he/she
is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A
\S 68-11-1601, et seq., and that the responses to this application or any other questions
deemed appropriate by the Health Services and Development Agency are true and
complete.
SIGNATURE/TITLE
Sworn to and subscribed before me this 15^{++} day of 8^{-+} day of 9^{-+} 9^{-+} a Notary
Public in and for the County/State of Navidson County Sennessee.
Sharrow C. Couch
NOTARY PUBLIC
My commission expires,,,,,,,
My Commission Expires MAR, 8, 2018

Attachment A, Item 3

Organizational Documents



PAGE 1

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF

DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT

COPY OF THE CERTIFICATE OF FORMATION OF "SUMNER REGIONAL MEDICAL

CENTER, LLC", FILED IN THIS OFFICE ON THE NINETEENTH DAY OF MAY,

A.D. 2010, AT 4:11 O'CLOCK P.M.

4825590 8100

100536424

AUTHENTICATION: 8005193

DATE: 05-20-10

You may verify this cartificate online at corp. delaware.gov/authver.shtml

State of Delaware Secretary of State Division of Corporations Delivered 04:25 PM 05/19/2010 FTLED 04:11 PM 05/19/2010 SRV 100536424 - 4825590 FTLE

Certificate of Formation of Summer Regional Medical Center, LLC

The undersigned, an authorized natural person, for the purpose of forming a limited liability company, under the provisions and subject to the requirements of the State of Delaware, particularly Chapter 18, Title 6 of the Delaware Code and the acts amendatory thereof and supplemental thereto, and known, identified, and referred to as the Delaware Limited Liability Company Act (the "Act"), hereby certifies that:

FIRST: The name of the limited liability company is Summer Regional Medical Center, LLC (the "Company").

SECOND: The address of the registered office and the name and address of the registered agent of the Company required to be maintained by Section 18-104 of the Act is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation as of May 19, 2010.

Mary Klim E. Shipp Authorized Person



STATE OF TENNESSEE Tre Hargett, Secretary of State

Division of Business Services William R. Snodgrass Tower 312 Rosa L. Parks AVE, 6th FL Nashville, TN 37243-1102

BUTLER SNOW LLP

ATTN: DAN H. ELROD

STE 1600

150 3RD AVE S

NASHVILLE, TN 37201-2046

Request Type: Certificate of Existence/Authorization

Request #:

0136177

Issuance Date: 08/13/2014

Copies Requested:

August 13, 2014

Document Receipt

Receipt #: 1610055

Filing Fee:

\$20.00

Payment-Check/MO - BUTLER SNOW LLP, RIDGELAND, MS

\$20.00

Regarding:

Sumner Regional Medical Center, LLC

Filing Type:

Limited Liability Company - Foreign

Formation/Qualification Date: 05/25/2010

Status:

Active

Duration Term:

Perpetual

Control #:

632152

Date Formed:

05/19/2010

Formation Locale: DELAWARE

Inactive Date:

CERTIFICATE OF AUTHORIZATION

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

Sumner Regional Medical Center, LLC

- * is a Limited Liability Company formed in the jurisdiction set forth above and is authorized to transact business in this State:
- * has paid all fees, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
- * has filed the most recent annual report required with this office;
- * has appointed a registered agent and registered office in this State;
- * has not filed an Application for Certificate of Withdrawal.

Secretary of State

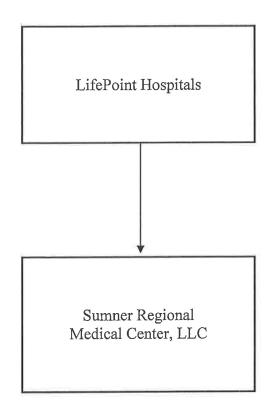
Processed By: Nichole Hambrick

Verification #: 008304628

Phone 615-741-6488 * Fax (615) 741-7310 * Website: http://tnbear.tn.gov/

Attachment A, Item 4

Organizational Chart



Note: This chart shows only the entities pertinent to the application. It is not possible to produce a chart that includes all 58 hospitals operated by LifePoint, but a list of LifePoint hospitals in Tennessee is attached.

LifePoint Hospitals in Tennessee

Livingston Regional Hospital 315 Oak Street Livingston, TN 38570

Riverview Regional Medical Center 158 Hospital Dr Carthage, TN 37030

Southern Tennessee Regional Healthy System at Lawrenceburg 1607 South Locust Ave Lawrenceburg, TN 38464

Southern Tennessee Regional Health System at Sewanee 1260 University Ave Sewanee, TN 37375

Southern Tennessee Regional Health System at Pulaski 1265 East College Street Pulaski, TN 38478

Southern Tennessee Regional Health System at Winchester 185 Hospital Rd Winchester, TN 37398

Starr Regional Medical Center 1114 West Madison Ave Athens, TN 37303

Starr Regional Medical 886 Highway 411 North Etowah, TN 37331

Sumner Regional Medical Center 555 Hartsville Pike Gallatin, TN 37066

Trousdale Medical Center 500 Church Street Hartsville, TN 37074

Attachment A, Item 6

Deed

RECORDED ELECTRONICALLY

ID 10 710 8 D County Suma(

Date 12.3-13 Time 3 11 Pm

simplifile www.simplifile.com 800.460.5657

FROM: Citadel Properties V, L.L.C.

TO:

Sumner Regional Medical Center, LLC

Address New Owner as Follows:

Send Tax Bills To:

Map-Parcel No.

Sumner Regional Medical Center, LLC,

SAME

Map 137, Parcels 8.01, 8.02, 8.03 and 8.04

a Delaware limited liability company c/o Lifepoint Hospitals

c/o Lifepoint Hospitals
103 Powell Court

Brentwood, TN 37027

THIS INSTRUMENT PREPARED BY: Waller Lansden Dortch & Davis, LLP, 511 Union Street, Suite 2700, Nashville, Tennessee 37219-1760

STATE OF TENNESSEE
COUNTY OF Williamson

The actual consideration or value, whichever is greater, for this transfer is

Affiant

\$18,000,000,000. Carrons state of state

and sworn to before me, this the

)

day of November, 2013.

Notary Public

My Comm. Expires:

SPECIAL WARRANTY DEED

KNOW ALL MEN BY THESE PRESENTS, that for and in consideration of the sum of TEN DOLLARS (\$10.00) cash in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, CITADEL PROPERTIES V, L.L.C., an Illinois limited liability company ("Grantor"), has bargained and sold, and by these presents does transfer and convey unto SUMNER REGIONAL MEDICAL CENTER, LLC a Delaware limited liability company ("Grantee"), the successors and assigns of Grantee, that certain tract or parcel of land in Sumner County, Tennessee, described on Exhibit A attached hereto and incorporated herein (the "Property"), subject to, however, those exceptions and encumbrances set forth on Exhibit B attached hereto and incorporated herein.

This is improved property known as 225 Big Station Camp Boulevard, Gallatin, Tennessee 37066.

TO HAVE AND TO HOLD the Property together with all appurtenances and hereditaments thereunto belonging or in any wise appertaining to Grantee, the heirs, representatives, successors and assigns of Grantee, forever.

Grantor further covenants and binds itself, its representatives, successors and assigns to warrant and forever defend the title to the Property to Grantee, the heirs, representatives, successors and assigns of Grantee, against the lawful claims of all persons whomsoever claiming by, through or under Grantor but excluding the claims of persons claiming by, through or under any current tenant of Grantor under the leases and set forth on Exhibit B, but not further or otherwise subject to the matters set forth on Exhibit B.

Wherever used, the singular number shall include the plural, the plural the

singular, and the use of any gender shall be applicable to all genders.
IN WITNESS WHEREOF, this instrument has been executed this 27th day of November, 2013.
CITADEL PROPERTIES V. L.L.C., a Illinois limited liability company By:
Name: David L. Varising Title: Sole Manager
STATE OF <u>Illinois</u>) COUNTY OF <u>Lake</u>)
Before me, a Notary Public in and for said State and County, duly commissioned and qualified, personally appeared <u>David Varwig</u> , with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged himself/herself to be the <u>Sole Manager</u> of Citadel Properties V, L.L.C., the within named bargainor, a limited liability company, and that (s)he executed the foregoing instrument for the purposes therein contained, by signing the name of the limited liability company by himself/herself as <u>Sole Manager</u> .
Witness my hand, at office, this The day of Manenther, 2013.
My Commission Expires: 3-1/-14 Notary Bublic OFFICIAL SEAL CAROLYN L. JELKS NOTARY PUBLIC - STATE OF ILLINOIS MY COMMISSION EXPIRES MAR 11, 2014

EXHIBIT A

Legal Description

LAND IN THE FOURTH CIVIL DISTRICT OF SUMNER COUNTY, TENNESSEE. BEING THE PROPERTY OF SUMNER REGIONAL HEALTH SYSTEMS, INC., AS OF RECORD IN BOOK 2635, PAGE 828, REGISTER'S OFFICE SUMNER COUNTY, TENNESSEE AND RECORD BOOK 2718, PAGE 773, REGISTER'S OFFICE SUMNER COUNTY, TENNESSEE, DESCRIBED MORE PRECISELY AS FOLLOWS:

BEGINNING AT A POINT AT A HIGHWAY MONUMENT ON THE NORTHERN RIGHT-OF-WAY OF LOWER STATION CAMP CREEK ROAD, SAID POINT BEING LOCATED ON THE WESTERN RIGHT-OF-WAY OF STATE ROUTE 386 AND BEING THE SOUTHEAST CORNER OF THIS PARCEL;

THENCE WITH THE NORTHERN RIGHT-OF-WAY OF LOWER STATION CAMP CREEK ROAD AND A CURVE TO THE LEFT, DELTA OF 14'31'46", RADIUS OF 625.00 FEET, LENGTH OF 158.49 FEET AND A CHORD BEARING OF N 75'06'13" W 158.07 FEET TO AN IRON ROD ON THE NORTHERN RIGHT-OF-WAY OF SAID ROAD;

THENCE LEAVING SAID ROAD, N 08'59'01" E 2000.68 FEET TO AN IRON ROD ON THE SOUTHERN MARGIN OF NEW STATION CAMP CREEK ROAD;

THENCE, S 4254'44" E 718.20 FEET TO AN IRON ROD ON THE SOUTHERN RIGHT OF-WAY OF NEW STATION CAMP CREEK ROAD;

THENCE, S 47'03'45" W 24.95 FEET TO A POINT AT A HIGHWAY MONUMENT AND THE RIGHT-OF-WAY OF STATE ROUTE 386;

THENCE WITH THE RIGHT-OF-WAY OF STATE ROUTE 386 FOR THE NEXT EIGHT CALLS:

S 34'24'24" E 101.12 FEET TO A POINT AT A HIGHWAY MONUMENT;

\$41'55'01" B 168.45 FEET TO A POINT AT A HIGHWAY MONUMENT;

CHORD BEARING OF S 09'38'23" E 203.13 FEET, RADIUS OF 185.00 FEET AND A LENGTH OF 215.03 FEET TO A POINT AT A HIGHWAY MONUMENT;

S 23'39'29" W 292.22 FEET TO A POINT AT A HIGHWAY MONUMENT;

S 26'23'25" W 228.79 FEET TO A POINT AT A HIGHWAY MONUMENT;

CHORD BEARING OF S 35'21'34" W 85'59 FEET, RADIUS OF 743.51 FEET AND A LENGTH OF 85.63 FEET TO A POINT AT A HIGHWAY MONUMENT;

S 4549'36" W 228.57 FEET TO A POINT AT A HIGHWAY MONUMENT;

S 47'53'25" W 541.42 FEET TO THE POINT OF BEGINNING;

CONTAINING 24.58 ACRES, MORE OR LESS.

Being the same property conveyed to Citadel Properties V, L.L.C., an Illinois limited liability company, by deed from SRHS Bankruptcy, Inc., of record in Record Book 3731, page 187, Register's Office for Sumner County, Tennessee.

EXHIBIT B

Permitted Exceptions

- 1. Taxes for 2013 and subsequent years.
- 2. Declaration of Easement and Maintenance Agreement of record in Record Book 2733, page 441, said Register's Office.
- 3. Water/sewer easement of record in Record Book 1343, page 417, said Register's Office.
- 4. Public Utility easement of record in Record Book 1481, page 228, said Register's Office.
- 5. Grant of Transmission Line Easement of record in Deed Book 174, page 370, said Register's Office.
- 6. Lease (Outpatient Diagnostic Center) dated April 1, 2007, between Citadel Properties V, L.L.C. and Sumner Regional Health Systems, Inc., successor in interest to Sumner Regional Medical Center, Inc., for approximately 11,757 square feet of diagnostic center space.
- 7. Lease (Clinic Space) dated April 1, 2007, between Citadel Properties V, L.L.C. and Sumner Regional Health Systems, Inc., successor in interest to Sumner Regional Medical Center, LLC for approximately 8,304 square feet of clinic space.
- 8. Matters shown on survey prepared by L. Steven Bridges, Jr., as Job N. 3218, dated September 27, 2013, last revised November 5, 2013.
- 9. Laws and ordinances affecting the Property.

Pamela L. Whitaker, Register

922259 Req #:

Summer County Tennesses Instrument #: 1071080

Rea'd: State: 66600.00 1.00 Clerk:

12/3/2013 at 3:11 PM in Record Book

Total: 66628.00 3877

FROM:

Citadel Properties V, L.L.C.

Pages 594-598

FORWARDED TO SUMMER COUNTY ASSESSOR OF PROPERTY ON DATE OF RECORDING

TO:

Sumner Regional Medical Center, LLC

Address New Owner as Follows:

Send Tax Bills To:

Map-Parcel No.

Sumner Regional Medical Center, LLC, a Delaware limited liability company

SAME

Map 137, Parcels 8.01, 8.02, 8.03 and 8.04

c/o Lifepoint Hospitals

103 Powell Court

Brentwood, TN 37027

THIS INSTRUMENT PREPARED BY: Waller Lansden Dortch & Davis, LLP, 511 Union Street, Suite 2700, Nashville, Tennessee 37219-1760

STATE OF TENNESSEE COUNTY OF Williams

The actual consideration or value, whichever is greater, for this transfer is

\$18,000,000,00. Car Affiant

and sworn to before me, this the 🖸

minission Expires Sept My Comm. Expires:

SPECIAL WARRANTY DEED

KNOW ALL MEN BY THESE PRESENTS, that for and in consideration of the sum of TEN DOLLARS (\$10.00) cash in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, CITADEL PROPERTIES V, L.L.C., an Illinois limited liability company ("Grantor"), has bargained and sold, and by these presents does transfer and convey unto SUMNER REGIONAL MEDICAL CENTER, LLC a Delaware limited liability company ("Grantee"), the successors and assigns of Grantee, that certain tract or parcel of land in Sumner County, Tennessee, described on Exhibit A attached hereto and incorporated herein (the "Property"), subject to, however, those exceptions and encumbrances set forth on Exhibit B attached hereto and incorporated herein.

This is improved property known as 225 Big Station Camp Boulevard, Gallatin, Tennessee 37066.

TO HAVE AND TO HOLD the Property together with all appurtenances and hereditaments thereunto belonging or in any wise appertaining to Grantee, the heirs, representatives, successors and assigns of Grantee, forever.

1

Grantor further covenants and binds itself, its representatives, successors and assigns to warrant and forever defend the title to the Property to Grantee, the heirs, representatives, successors and assigns of Grantee, against the lawful claims of all persons whomsoever claiming by, through or under Grantor but excluding the claims of persons claiming by, through or under any current tenant of Grantor under the leases and set forth on Exhibit B, but not further or otherwise subject to the matters set forth on Exhibit B.

Wherever used, the singular number shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders.

IN WITNESS WHEREOF, this instrument has been executed this 27th day of November, 2013.

	CITADEL PROPERTIES V. L.L.C., a Illinois limited liability company
	By:
*	Name: David L. Varuing Title: Sote Manager
STATE OF Illinois) COUNTY OF Lake)	

COUNTY C Before me, a Notary Public in and for said State and County, duly commissioned and

qualified, personally appeared David Varwig, with whom I am personally acquainted (or proved to me on the basis of satisfactory evidence), and who, upon oath, acknowledged himself/herself to be the Sole Manager of Citadel Properties V, L.L.C., the within named bargainor, a limited liability company, and that (s)he executed the foregoing instrument for the purposes therein contained, by signing the name of the limited liability company by himself/herself as Sole Manager.

Witness my hand, at office, this Ith day of Maneulles

My Commission Expires: 3-11-14

OFFICIAL SEAL CAROLYN L JELKS

NOTARY PUBLIC - STATE OF ILLINOIS MY COMMISSION EXPIRES MAR 11, 2014

2

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- 8. Matters shown on survey prepared by L. Steven Bridges, Jr., as Job N. 3218, dated September 27, 2013, last revised November 5, 2013.
- 9. Laws and ordinances affecting the Property.

4

True Copy Certification

I, Mark Lee, do hereby make oath that I am a licensed attorney and/or the custodian of the electronic version of the attached document tendered for registration therewith and that this is a true and correct copy of the original documents executed and authenticated according to law.

Mark L...
Signature

State of Tennessee

County of Shelby

Personally appeared before me, Michele U. Clark. a notary public for this county and state, Mark Lee, who acknowledges that this certification of an electronic document is true and correct and whose signature I have witnessed.

Mechel M. Clark
Notary's Signature

My Commission Expires: 7-14-2017

Notary Seal:



Attachment B, II, E, 1

FDA Approval

KO81-196



GF Healthcare

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR

Device Name

Proprietary Device Name:

Discovery XR and XA Diagnostic Imaging

Systems

Date prepared:

April 4, 2008

Establishment Name and Registration Number of Submitter

Name:

GE Healthcare

3000 N. Grandview Blvd. Waukesha, WI 53188

Registration Number: Corresponding Official: 2126677

D. Duersteler

GE Healthcare P.O. Box 414

Milwaukee, WI 53201 Phone: 262-312-7029 FAX: 262-312-7144

Email: david.duersteler@med.ge.com

Device Classification

Classification Code: Panel Identification: 90 KPS/90 JAK Radiology

Classification Name:

Emission Computed Tomography

System/Computed Tomography X-ray System (Per 21CFR 892.1200 and 21CFR 892.1750)

Common Name:

Classification Class:

PET/CT Imaging System Class II Product

Reason for 510(k) Submission:

Modification to existing device

Device Description

The Discovery XR and XA are integrated multi-slice Computed Tomography and Positron Emission Tomography scanners. They use CT images to correct for non-uniform attenuation of the PET images and integrated CT and PET images to localize emission activity in the patient anatomy. Discovery XR and XA have capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated graphical user interface. Discovery XR and XA can also be used as a stand-alone head and whole body multislice CT diagnostic imaging system.

Identification of Legally Marketed Equivalent Devices

GE Healthcare

Discovery VCT

K050559

General Electric Company P.O. Box 414 Milwaukee, WI 53201



510(k) Summary of Sofety and Effectiveness April 4, 2008 Page 2

Comparison with Predicate Device

The GE Discovery XR and XA Systems are the same as the above predicate device in that they combine a CT and PET scanner system to produce head and whole body attenuation corrected PET images and localization of emission activity in patient anatomy by means of integrated PET and CT images. They employ the same basic major components including integrate PET and CT gantris, patient table, operator console for analysis and display, and a power distribution unit. The fundamental technology of detecting photons emitted from the patient as a result of positron emitting PET tracers creating coincidence events that are detected by a scintillator material and photodetector is the same as the predicate device. The GE Discovery XR and XA differ from the Discovery VCT in the design of the PET gantry subsystem acquisition electronics, an additional optional reconstruction mode, specific CT models integrated with the system, and improved user interface.

Indications for Use of Device

The GE Discovery XR and XA Systems are intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery XR and XA are to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. These devices can also assist in radiotherapy planning.

The Discovery XR and XA can also be used as stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging systems.

Conclusion

In the opinion of GE Healthcare, the GE Discovery XR and XA Systems are substantially the same in design, materials, energy sources, and technology, do not introduce new safety concerns, perform as well as currently marketed devices, and are therefore substantially equivalent in terms of safety and effectiveness to the currently marketed Discovery VCT System.

General Electric Company P.O. Box 414 Milwaukee, WI 53201



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 1 2 2008

GE Medical Systems. LLC % Mr. Daniel W. Lehtonen Responsible Third Party Official Intertek Testing Services 2307 E. Aurora Rd., Unit B7 TWINSBURG OH 44087

Re: K081496

Trade/Device Name: Discovery XR and XA Diagnostic Imaging Systems

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission computed tomography system

Regulatory Class: II Product Code: KPS Dated: May 28, 2008 Received: May 29, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the <u>Code of Federal Regulations</u>, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other	8 v v	240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Y ancyc Grados

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 201476

Device Name: Discovery XR and XA Diagnostic Imaging Systems

Indications for Use:

The GE Discovery XR and XA Systems are intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery XR and XA are to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. These devices can also assist in radiotherapy planning.

The Discovery XR and XA can also be used as stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging systems.

Prescription Use __X_ Over-The-Counter Use ____ (Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Attachment B, II, E, 2

Vendor Quote

Ouotation Number: PR5-C23806 V 4

Sumner Regional Medical Center LLC 555 Hartsville Pike Gallatin TN 37066-2400 Attn: Frank Givens
Director of Radiation Oncology
Radiation Oncology
555 Hartsville Pike
Gallatin TN 37066

Date: 08-29-2014

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warrantylies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

• Terms of Delivery:

FOB Destination

• Quotation Expiration Date:

11-21-2014

• Billing Terms:

80% on Delivery/ 20% on Acceptance or First Patient Use

• Payment Terms:

NET 30

Governing Agreement:

LifePoint Corporate Services

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare

3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GΕ	HEA	LTH	ICA	RE

Bryan Fondrie

08-29-2014

Product Sales Specialist

US

Phone: +1 262 352 1354 Fax: 414-918-8543 Bryan,Fondrie@ge.com

CUSTOMER

Authorized Customer Date

Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually

INDICATE FORM OF PAYMENT:

(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)

____Cash * ____Lease ____HFS Loan

If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.



1/5

GE Healthcare Confidential and Proprietary General Electric Company, GE Healthcare Division 3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE Healthcare

QUOTATION

Quotation Number: PR5-C23806 V 4

agreed upon by the parties.



Quotation Number: PR5-C23806 V 4

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
	1		Optima PETCT 560			
1	1	S9216OB	OPTIMA PETCT 560 16SL STD	\$2,250,000.00	58.48%	\$934,107.24
2	1	S9100YT	NAF18 PET PROMO	\$100,000.00	58.48%	\$41,515.88
3	1	S5052MO	ASIR option for NIO 16sl system - Promotion	\$175,000.00	58.48%	\$72,652.79
4	1	P5051TF	PET/CT Long Length Cables	Incl.	Incl.	Incl.
5	1	B7877BC	Bar Code Reader -USB	\$1,000.00	58.48%	\$415.16
6	1	B77292CA	CT Service Cabinet	Incl.	Incl.	Incl.
7	1	B77322CA	CT CHAIR NO ARMREST	\$721.46	58.48%	\$299.53
8	1	P5051LZ	WideView software option for Discovery PET/CT	\$50,000.00	58.48%	\$20,757.94
9	1	E6315JE	DIACOR RTP Flat Tabletop for CT and PET/CT Systems - RT16, DVCT, Disc 600/690, HD750 and VCT	\$15,000.00	21.00%	\$11,850.00
10	1	E4502F	14 KVA 3-Phase Partial UPS for VCT	\$27,000.00	21.00%	\$21,330.00
11	1	E4502AB	90 Amp Main Disconnect Panel for CT	\$7,349.00	21.00%	\$5,805.71
12	1	E8690AF	Discovery PET/CT 600 Pin Source	\$8,000.00	21.00%	\$6,320.00
13	1	E8500NB	Patient Arm Support System for Nuclear, PET/CT, MRI	\$675.00	21.00%	\$533.25
14	1	E8008P	VQC Phantom for Volumetric Registration	\$3,500.00	21.00%	\$2,765.00
15	1	E8000HF	2 TB USB EXT HARD DRIVE	\$650.00	21.00%	\$513.50
			Quote Summary: Total Discount: (57.60%) Total Extended Selling Price: Customer Loyalty Discount Total Quote Net Selling Price			(\$1,520,029.46) \$1,118,866.00 \$1,093,866.00



GE Healthcare

QUOTATION

Quotation Number: PR5-C23806 V 4

Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)



Quotation Number: PR5-C23806 V 4

Options
(These items are not included in the total quotation amount)

Item No.	Qty	Catalog No.	Description	Ext Sell Price	Initial To Accept
16	1	P5051NC	Q.AC option	\$28,472.93	X
17	1	S7803CY	Oncology Workstation with Full SimMD	\$57,855.00	X
18	1	E8819KA	Varian RPM Respiratory Gating Device, GEHC installed	\$54,510.00	X
19	1	E8819HB	Varian RPM Mount for PET Global Table	\$711.00	Χ
20	1	E8007NJ	Medrad Stellant D Dual Flow Injector - Ceiling Mount (Long Post)	\$37,525.00	X
21	1	E8007PJ	OCS III MOUNTING PLATE	\$513.50	X
22	1	E8505R	LAP Dorado 3 Red Laser CARINAiso - Wall Mounted	\$41,866.05	X
23	1	E8505RC	LAP Dorado 3 Green Laser CARINAiso - Wall Mounted	\$52,926.05	Χ
24	1	W0105PT	TiP Applications PET/CT Succeed Advance Training Program	\$28,300.00	X

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)





GE Healthcare Additional Terms and Conditions: DoseWatch

GE Healthcare

1. Scope. These GE Healthcare Additional Terms and Conditions incorporate the GE Healthcare General Terms and Conditions, and any GE Healthcare Quotation that identifies the DoseWatch software licensed by Customer (collectively, referred to as the "Agreement").

2. Software and Device License.

2.1 <u>Software License</u>. GE Healthcare grants to Customer a non-exclusive, non-transferable, limited license to use in connection with a device (as defined herein) within the physical confines of the facility listed in the GE Healthcare Quotation for Customer's internal business purposes only, the GE Healthcare DoseWatch software and associated documentation provided hereunder by GE Healthcare to Customer, subject to the license scope and other restrictions set forth in this Agreement. This software license further authorizes the connection of the number of devices set forth in the GE Healthcare Quotation only to the DoseWatch software through Customer's secured network. As used herein, a "device" is defined as Customer equipment approved by GE Healthcare to be connected to the DoseWatch software under this Agreement. Additional connections of devices may be added to this Agreement subject to individual device licenses (as set forth below) at GE Healthcare's then current rates.

Customer may permit its employees, authorized agents and contractors to use the DoseWatch software and associated documentation consistent with this Agreement; provided, however, that Customer shall be solely responsible for any acts of its employees, agents and contractors which are inconsistent with this Agreement. Customer's affiliates may use the DoseWatch software only by agreeing to be bound by this Agreement and by paying any applicable license fees. Customer may make one (1) copy of the DoseWatch software solely for backup purposes, so long as applicable license fees are paid. Customer shall reproduce on such copy any and all notices, including copyright notices and any other proprietory legends that were on the original copy.

- 2.2 <u>Device License</u>. Each connection of a specific Customer device (as referenced above) to the DoseWatch software requires the purchase by Customer of a specific device license referencing a unique device ID which allows concurrent use of the DoseWatch software with the specific Customer device on Customer's network. The device license is unique per Customer device connected to the DoseWatch software at a specified Customer facility. The terms of the device license are generally identical to the terms of the software license. For avoidance of doubt, the device license is coterminous with the software license herein, and does not entitle Customer to any warranties distinct from and in addition to the limited warranties applicable to the DoseWatch software set forth in this Agreement.
- 2.3 <u>Restrictions.</u> Without GE Healthcare's prior written consent, Customer may not: (i) copy, sublicense, distribute, rent, lease, loan, resell, modify or translate the DoseWatch software or create derivative works based thereon; (ii) directly or indirectly decompile, disassemble, reverse engineer or otherwise attempt to learn the source code, structure, algorithms or ideas underlying the DoseWatch software; (iii) provide service bureau, time share or subscription services based on the DoseWatch software; (iv) remove, obscure or modify any markings, labels or any notice of the proprietary rights, including copyright, patent and trademark notices of GE Healthcare or its licensors; (v) electronically transfer the DoseWatch software outside Customer's network dedicated for the DoseWatch software; or (vi) release the results of any testing or benchmarking of the DoseWatch software. Customer will use the DoseWatch software only at the Customer facility listed in the GE Healthcare Quotation, and will not transfer the DoseWatch software from such facility without GE Healthcare's prior written permission.
- 2.4 Ownership. GE Healthcare and its licensors, as applicable, retain all ownership and intellectual property rights to the DoseWatch software and documentation. No license rights are granted (whether by implied license or otherwise) to Customer except as specifically provided in this Agreement. Customer acknowledges and agrees that all copyrights, trademarks, patents, trade secrets, and other proprietary rights in or related to the DoseWatch software and documentation are owned by GE Healthcare. If Customer is a U.S. Government agency, Customer acknowledges that the DoseWatch software licensed under this Agreement is a commercial item that has been developed at private expense and not under a Government contract. The Government's rights relating to the DoseWatch software are limited to those rights applicable to Customer as set forth herein and are binding on Government users in accordance with Federal Acquisition Regulation 48 C.F.R. Section 12.212 for non-defense agencies and/or Defense FAR Supplement 48 C.F.R. Section 227.7202-1 for defense agencies.
- 2.5 <u>Enhancements or Modifications</u>. GE Healthcare reserves the right to make changes to the DoseWatch software and documentation in its sole discretion in order to correct any errors or to incorporate any changes, modifications, improvements or enhancements that it deems necessary. All such enhancements and modifications to the DoseWatch software or documentation (even if such modifications, improvements or enhancements are made as a result of comments or requests by Customer) shall be and remain the sole property of GE Healthcare. Customer understands and agrees that GE Healthcare and its affiliates and subsidiaries will continue to license software and technology to other parties, to undertake developments and enhancements of such software and technology and generally to utilize proprietary engines, infrastructure codes and interfaces in designing solutions for other parties for use in connection with a variety of applications, including applications which may be similar in design, form and content to the applications relating to the DoseWatch software.
- 2.6 <u>Documentation</u>. Customer shall have the right to reproduce solely for its own internal use, the documentation furnished by GE Healthcare pursuant to this Agreement. All copies of such documentation made by Customer shall include any proprietary notice or stamp and any copyright notice that has been affixed by GE Healthcare to the original. All copies of the documentation must be returned to GE Healthcare within thirty (30) days of the termination or expiration of this Agreement.

3. Delivery, Implementation, Testing and Acceptance.

3.1 <u>Delivery.</u> Delivery dates are approximate. For GE Healthcare DoseWatch software or documentation, delivery means delivery to Customer's designated delivery location. For GE Healthcare services, delivery means the performance of such services by GE Healthcare. At the time of such delivery, Customer will pay GE Healthcare for any amounts due upon delivery. The DoseWatch software is licensed to

Customer; no title to or other ownership interest in the DoseWatch software passes to Customer.

- 3.2 <u>Implementation</u>. GE Healthcare shall perform any installation, implementation, configuration and optimization services as set forth in the GE Healthcare Quotation. Such services will be performed in accordance with applicable GE Healthcare installation and implementation guides, project plans and/or statements of work. Customer agrees to review the applicable installation and implementation guides and project plans and/or statements of work and perform its obligations set forth in those materials. For the avoidance of doubt, any services identified in a GE Healthcare Quotation are a required component of the Quotation and of the overall consideration between GE Healthcare and Customer. Such services are not optional.
- 3.3 Testing and Acceptance. Commencing on the date that GE Healthcare gives notice of installation of the DoseWatch software (or on the date as otherwise provided for in the applicable statement of work) and implementation by GE Healthcare, Customer will have thirty (30) days to test the DoseWatch software. Customer shall be deemed to have accepted the DoseWatch software the earlier of: (i) Customer's written acceptance, which shall not be unreasonably withheld, delayed or conditioned by Customer; (ii) the expiration of the test period identified in the preceding sentence without GE Healthcare receiving written notice from Customer of the existence of any errors and a reasonable description of such error(s); or (iii) the date Customer first uses the DoseWatch software to process actual data in the operation of Customer's business (e.g., the transfer of patient-dose data from a Customer device to the DoseWatch software database). As used in this Section, an "error" is the failure of the DoseWatch software to perform substantially in accordance with the documentation. Testing will be conducted using test data, preferably from Customer's historical operations, in a non-productive environment and according to GE Healthcare's testing specifications. Upon discovering an error, Customer shall promptly notify GE Healthcare in writing of the error, which notice shall include a reasonable description of the error. Upon GE Healthcare's timely receipt of Customer's written notice, GE Healthcare shall use commercially reasonable efforts to correct such error identified by Customer therein. An acceptance test for amendments or alterations provided by GE Healthcare as a result of testing may be conducted by Customer for a period of not more than five (5) days after delivery of such amendment or alteration, and the test period shall be extended for this purpose. Upon the occurrence of acceptance, all payments associated with acceptance, if any, shall be due and payable without further notice or demand.
- **4. Warranties and Remedies.** The following warranties apply only to the DoseWatch software and are in lieu of any other standard GE Healthcare warranties.
- 4.1 Express Warranties. GE Healthcare makes the following express warranties to Customer:
 - 4.1.1. Except as indicated otherwise below, GE Healthcare warrants that; (i) GE Healthcare has the right to license or sublicense the DoseWatch software to Customer subject to the terms and conditions set forth herein; (ii) for ninety (90) days following the warranty commencement date (as defined herein), the DoseWatch software will perform substantially in accordance with the applicable documentation; (iii) it has not inserted any disabling code (as defined herein) into the DoseWatch software; and (iv) it will use commercially reasonable efforts consistent with industry standards to scan for and remove any software viruses prior to delivery of the DoseWatch software. As used herein, "warranty commencement date" means the date upon which Customer accepts the DoseWatch software (as set forth in Section 3.3 above), and "disabling code" means computer code that is designed to delete, interfere with, or disable the normal operation of the DoseWatch software; provided, however, that code included in the DoseWatch software that prohibits use outside of the license scope will not be deemed to be disabling code. The warranty period for any software or component furnished to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced software.
 - 4.1.2. Except for the warranty set forth in Section 4.1.1(i), the above warranties do not cover hardware, equipment or third-party software delivered with the DoseWatch software. Third-party software, if applicable, is identified with a separate part number on the GE Healthcare Quotation (i) delivered to Customer in the third-party manufacturer/supplier's packaging and with its labeling, or (ii) for which GE Healthcare expressly indicates (either in the GE Healthcare Quotation or in the product documentation) that the DoseWatch software or equipment is provided with the third-party manufacturer/supplier's warranty in lieu of a GE Healthcare warranty. Such products are only covered by the third-party manufacturer/supplier's warranties, to the extent available.
- 4.2 <u>No Other Warranties.</u> NO OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUIET ENJOYMENT, SYSTEM INTEGRATION OR DATA ACCURACY, WILL APPLY.
- 4.3 <u>Sole and Exclusive Remedies for Breach of Warranties</u>. The remedies set forth below are Customer's sole and exclusive remedies and GE Healthcare's sole and exclusive liability for warranty claims. These exclusive remedies shall not have failed of their essential purpose (as that term is used in the Uniform Commercial Code) as long as GE Healthcare remains willing to repair or replace defective warranted DoseWatch software for no charge, as applicable, within a commercially reasonable time after being notified of Customer's warranty claim.
 - 4.3.1. If there is a breach of the warranty in Section 4.1.1(i), GE Healthcare will indemnify Customer in accordance with Section 3 (IP Indemnification) of the General Terms and Conditions included as part of this Agreement.
 - 4.3.2. If there is a breach of a warranty in Section 4.1.1(ii) (iv), and Customer promptly notifies GE Healthcare of Customer's warranty claim during the warranty period and makes the DoseWatch software available for warranty service, GE Healthcare will, at its option, with respect to the DoseWatch software, either correct the non-conformity or replace the applicable software. Unless agreed otherwise, warranty service will be performed without charge from 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel. For certain licensed software, GE Healthcare will perform warranty service only at an authorized service center or, in some instances, via a secure, remote connection to a GE Healthcare online center.
- 4.4 <u>Limitations</u>. GE Healthcare shall not have any obligation to Customer hereunder if the warranty claim results from or arises out of: (i) the use of the DoseWatch software in combination with any software, tools, hardware, equipment, supplies, accessories or any other materials or services not furnished by GE Healthcare or recommended in writing by GE Healthcare; (ii) the use of the DoseWatch software in a manner or environment, or for any purpose, for which GE Healthcare did not design or license it, or in violation of GE Healthcare's written recommendations or instructions on use; (iii) any alteration, modification or enhancement of the DoseWatch software by Customer or any third party not authorized or approved in writing by GE Healthcare; (iv) inadequate back-up or virus protection or any other cause external to the DoseWatch software or beyond GE Healthcare's reasonable control. In addition, the warranties set forth above do not cover the DoseWatch

software to the extent it is used in any country other than the country to which GE Healthcare ships or delivers the DoseWatch software (unless GE Healthcare expressly agrees otherwise in writing). GE Healthcare does not guarantee nor does it warrant that the DoseWatch software will operate without error or interruption, or that the DoseWatch software will provide accurate or complete results.

5. Professional Services.

- 5.1 <u>Statement of Work.</u> Following execution of this Agreement by the parties, the parties may enter into a written statement of work ("SOW") signed by the parties that describe the professional services to be provided pursuant to the GE Healthcare Quotation, which may include, among other things, an installation, implementation, configuration, and optimization project work plan, and other related professional services. GE Healthcare shall perform the professional services and provide any deliverables described in any such SOW and shall use commercially reasonable efforts to do so according to any delivery schedule in the SOW. In the event there is a conflict between the terms and conditions of this Agreement and the terms and conditions of a SOW, the terms and conditions of the SOW shall prevail with respect to the subject matter of the SOW. A SOW may only be modified in writing signed by authorized representatives of both parties and must be made pursuant to mutually agreed change control procedures. Changes to a SOW may require a change in fees reflecting the change in scope and/or change in schedule of delivery of the professional services or deliverables and/or change in Customer's responsibilities.
- 5.2 <u>Project Managers</u>. If required by the SOW, Customer and GE Healthcare shall each designate a project manager who will be responsible for day-to-day communications regarding the subject matter of the applicable SOW. The project managers will be responsible for monitoring the schedules and progress of professional services pursuant to the Agreement and/or SOW and will have the authority to act for the respective parties in all aspects of the engagement. The project managers for the parties will meet in person or via conference call as necessary. Any additional responsibilities of the project managers shall be set forth in the SOW.
- 5.3 Ownership Rights. GE Healthcare shall retain sole ownership of all deliverables (including any intellectual property embodied in the deliverables or related to them) and any intellectual property developed under a SOW or during the course of performing the services whether or not the services are performed by GE Healthcare alone or jointly with Customer or others. In addition, GE Healthcare shall own all improvements, enhancements and derivative works of the DoseWatch software and any GE Healthcare intellectual property created under the SOW. Customer hereby irrevocably assigns, transfers and conveys, and hereby causes Customer's employees, agents and contractors to irrevocably assign, transfer and convey, to GE Healthcare all of Customer's rights in and to such deliverables and intellectual property. During the term of this Agreement, GE Healthcare grants to Customer a nonexclusive, nontransferable, limited license, without the right to sublicense, to use the deliverables solely for Customer's internal business purposes and subject to the limitations described in this Agreement and the applicable SOW. Customer agrees to provide reasonable assistance to GE Healthcare in obtaining and enforcing GE Healthcare's rights to such deliverables and intellectual property without any obligation of GE Healthcare to pay compensation or royalties. GE Healthcare will acquire no rights to any of Customer's confidential information that may be included in any deliverable unless expressly agreed to otherwise by Customer.
- 6. Medical Diagnosis and Treatment. All clinical and medical treatment and/or diagnostic decisions are the sole responsibility of Customer and its licensed and unlicensed healthcare employees, agents and contractors (collectively, "Healthcare Staff"). Customer acknowledges and agrees that: (i) GE Healthcare is in no way responsible for the clinical and medical treatment and/or diagnostic decisions made by Customer and its Healthcare Staff; (ii) it is Customer's sole and non-delegable duty to have properly trained and fully qualified Healthcare Staff operate the DoseWatch software, and that this duty is non-delegable to GE Healthcare; (iii) the DoseWatch software does not make clinical, or other decisions and is not a substitute for competent, properly trained and knowledgeable Healthcare Staff who bring professional judgment and analysis to the information presented by the software; (iv) Customer and its Healthcare Staff are solely responsible for verifying the accuracy of all patient information and determining the data necessary to make medical and diagnostic decisions, as well as for complying with all laws, regulations and licensing requirements applicable to its delivery of healthcare services; (v) Customer is solely responsible for establishing and maintaining reasonable quality control procedures to ensure the accuracy of input to the DoseWatch software; (vi) Customer and its Healthcare Staff will consider all relevant information including information presented by the DoseWatch software and may give whatever weight its deems appropriate to the information produced by the DoseWatch software in the performance of Customer's and its Healthcare Staff's functions; and (vii) Customer has reviewed and will communicate to its Healthcare Staff who use and access the DoseWatch software any software information, which may be provided to Customer by GE Healthcare from time to time.
- 7. Customer Responsibilities. In order for GE Healthcare to perform its obligations under this Agreement (including warranty obligations), Customer agrees to:
 - (a) Provide, prepare and maintain a suitable, safe and hazard-free location and environment for the DoseWatch software, devices, and warranty services in material compliance with any written requirements provided by GE Healthcare; perform GE Healthcare recommended routine maintenance and operator adjustments; for software and products that will be operated on or in connection with Customer supplied hardware or equipment, Customer is responsible for ensuring that its hardware and equipment conform with GE Healthcare's minimum hardware requirements as made available to Customer; and ensure that any non-GE Healthcare provided service is performed by, and GE Healthcare products are used by, qualified personnel in accordance with applicable user documentation.
 - (b) Enabling the connectivity and interoperability between Customer supplied hardware or software or other systems or devices and the DoseWatch software, including, without limitation, procuring and installing any modifications, interfaces or upgrades consistent with GE Healthcare's written specifications and applicable statements of work; ensuring that Customer's network is adequate for the proper operation and performance of the DoseWatch software and that it otherwise meets GE Healthcare's network configuration requirements (including requirements for preparation of Customer's facility, remote interconnections and Internet Protocol address assignments) provided by GE Healthcare to Customer.
 - (c) Provide GE Healthcare prompt and unencumbered access (onsite and remote) to the DoseWatch software, devices connected to the DoseWatch software, network cabling and communication equipment as necessary to perform warranty services. This access includes providing and maintaining connectivity to the DoseWatch software (modern line, internet connection, VPN persistent access, broadband internet connection, or other secure remote access reasonably requested by GE Healthcare) to permit GE Healthcare to

- perform warranty services, including remote diagnostic, monitoring and repair services. GE Healthcare may separately charge Customer for a scheduled warranty service call where Customer does not provide such access and GE Healthcare is therefore required to schedule an additional warranty service call.
- (d) Establish and maintain security, virus protection, backup, data integrity, database maintenance and management, archiving and disaster recovery plans for any data, images, software or equipment (GE Healthcare shall not be responsible for any recovery of lost data or images). This responsibility includes maintaining secure network and network security components, firewalls and security-related hardware or software, preventing unauthorized access to the DoseWatch software and preventing interception of communications between GE Healthcare's service center and the DoseWatch software.

Unless expressly provided otherwise, Customer is separately responsible for: (a) the repair, replacement or removal of any disposables, consumables, supplies, accessories or collateral equipment; (b) the provision of or payment for any applicable rigging or facility cost; and (c) any service necessitated by (i) Customer's or its representative's designs, specifications, or instructions, (ii) anything external to the DoseWatch software, including any causes or events beyond GE Healthcare's reasonable control, (iii) DoseWatch software or device misuse, (iv) combining any component of the DoseWatch software or device with any incompatible equipment or software, or (v) Customer's relocation, additions, or changes to the DoseWatch software or device, unless GE Healthcare has consented in writing to such relocations, additions or changes.

8. Miscellaneous.

- 8.1 <u>Independent Contractor</u>. GE Healthcare and Customer are independent contractors and nothing contained in this Agreement is intended nor shall it be construed as creating a fiduciary relationship, partnership or joint venture between the parties, except as otherwise agreed in writing by the parties.
- 8.2 Effect of Termination/Expiration. In addition to the termination provisions of the GE Healthcare General Terms and Conditions, upon termination or expiration of this Agreement for any reason, Customer will, within thirty (30) days, unless otherwise agreed to in writing, deliver to GE Healthcare all of GE Healthcare property in Customer's possession, including but not limited to the DoseWatch software and all copies thereof, hardware, supplies, tools, equipment, records, files, documentation, and any other materials owned by GE Healthcare. Customer agrees to permanently delete all copies of the DoseWatch software from Customer facilities immediately upon termination/expiration of this Agreement and promptly provide GE Healthcare with written certification of such deletion. Customer shall also make payment on any outstanding payments owed to GE Healthcare within ten (10) days of the effective date of termination. For avoidance of doubt, Customer's license to the DoseWatch software shall immediately terminate upon the termination or expiration of this Agreement.
- 8.3 <u>Indemnification</u>. Customer will indemnify, defend and hold GE Healthcare harmless from and against any and all actions, suits, claims, demands, prosecutions, liabilities, costs, expenses, damages, deficiencies, losses or obligations (including attorneys' fees) based on or arising out of this Agreement and/or use of the DoseWatch software by Customer and/or its employees, agents or contractors (individually and collectively referred to as "Customer Representatives"), including without limitation any Customer Representative obligation or breach thereof, any death or personal injury caused by Customer Representatives, any misuse or unauthorized use or modification of the DoseWatch software by Customer Representatives, and any representation made or warranty given by Customer Representatives with respect to the DoseWatch software, services, patents, products, materials or technical information.
- 8.4 <u>Audit</u>. Upon ten (10) days' prior written notice to Customer, GE Healthcare may audit Customer's use of the DoseWatch software and Customer shall make available to GE Healthcare or GE Healthcare's designated representatives Customer data, books and records relating to its performance under this Agreement for the purpose of GE Healthcare verifying Customer's compliance with the terms and conditions of this Agreement. Customer agrees to cooperate with GE Healthcare's audit and to provide reasonable assistance and unrestricted access to such information. If the audit uncovers underpaid or unpaid fees owed to GE Healthcare, Customer agrees to pay those fees and GE Healthcare's costs incurred in conducting the audit within thirty (30) days of written notification of the amounts owed. If Customer does not pay the amounts owed, or the audit reveals that Customer is not in compliance with this Agreement, GE Healthcare may terminate this Agreement and Customer's license to use the DoseWatch software.
- 8.5 Relief for Breach. Customer agrees that a violation of GE Healthcare's license, confidentiality or intellectual property rights will cause irreparable harm to GE Healthcare for which the award of money damages alone are inadequate. Customer agrees that in the event of any such violation, GE Healthcare shall be entitled to seek injunctive relief without the posting of a bond or other undertaking, in addition to immediately terminating the license granted herein and requiring that Customer cease use of and return the DoseWatch software and documentation, including all copies in any media, in addition to seeking any other legal or equitable remedies available to GE Healthcare. This Section shall survive the termination of this Agreement.



GE Healthcare

NOTICE REGARDING NUCLEAR MEDICINE PRODUCTS

This notice applies to the following GE Healthcare Nuclear Medicine products only: Discovery NM 670 and Discovery NM 630 (the "Products").

GE Healthcare has reclassified several advanced software tools and associated documentation to a GE Healthcare Technical Service Technology package that we feel will bring greater value and interest to our customers. GE Healthcare will continue to provide trained customer employees with access to the GE Healthcare Technical Service Technology package under a separate agreement.

GE Healthcare will continue to provide customers and their third party service providers with access to software tools and associated documentation in order to perform basic service on the Products upon a request for registration for such access. This will allow GE Healthcare to react faster to the future service needs of GE Healthcare customers.

If you have any questions, you can contact your sales Service Specialist.



GE Healthcare

For Third Party Products and Services Only: If GE Healthcare has agreed to provide any third party products and/or services (other than GE Healthcare accessories and supplies) to Customer as part of the Quotation, including but not limited to any Commitment Account/Non-Inventory items, (i) GE Healthcare is acquiring such products and/or services on Customer's behalf and not as a supplier of such products and/or services; (ii) GE Healthcare makes no warranties of any kind, express or implied, with respect to such products and/or services (warranties, if any, on such products and/or services will be provided by the manufacturer or service provider, as applicable); (iii) Customer is solely responsible for ensuring that the acquisition and use of such products and/or services is in compliance with applicable laws and regulations, including applicable FDA regulations; and (iv) Customer is solely responsible for any and all claims resulting from or related to the acquisition or use of such products and/or services.

For Mobile Systems Only: For products that are approved by GE Healthcare for use as transportable, relocatable and mobile systems, GE Healthcare will deliver the system to Customer's van manufacturer and furnish final assembly services to place the system in Customer's van. At the time of order, Customer must notify GE Healthcare of the van manufacturer to which the system is to be shipped. It is Customer's responsibility to make arrangements with the van manufacturer for delivery of the van and to comply with any additional planning requirements of the van manufacturer. For MR systems, GE Healthcare's product tests will be performed when assembly in the van is completed and MR system operation will be re-checked when the van is delivered to Customer.

For MR Products Only:

- a. MR Systems. Customer will provide a site and surroundings suitable for installation and operation of an MR system producing strong magnetic and electric fields, and Customer will be required to provide a water chiller meeting GE Healthcare specifications.
- b. Magnetic Resonance Imaging (MR) Site. Customer will provide a site and surroundings suitable for installation and operation of an MR system producing strong magnetic and electric fields, and Customer will be required to provide a water chiller meeting GE Healthcare specifications. Customer acknowledges that the magnetic fields of MR systems attract ferro-magnetic articles and are capable of rapidly accelerating such articles toward the magnet, creating corresponding physical danger to persons in the vicinity and possible damage to such systems. In addition, the magnetic and radio frequency fields of such systems may adversely affect the operation of pacemakers, equipment containing magnetic reed switches, and aneurysm or surgical clips.
- c. Magnet Maintenance and Cryogens. The price of MR systems includes all cryogens necessary for final assembly and testing of the MR system. Cryogen loss attributable to power loss or water chiller failure for the MR system's shield cooler or condenser system during installation is Customer's responsibility, and Customer will be billed for cryogen replacement plus the associated cryogen transfill labor at GE Healthcare's then applicable rates. After final assembly, Customer will be responsible to supply and install all cryogens, unless cryogen loss is caused by a defect in material or workmanship within the scope of GE Healthcare's applicable MR system warranty. Following final assembly, provided cryogen boil-off rates have not been adversely affected by actions of Customer, its representatives or contractors, or any third party not authorized by GE Healthcare, GE Healthcare will provide a super-conductive magnet which, at the expiration of the warranty period, has cryogen boil-off rates not exceeding those stated in GE Healthcare's applicable magnet specifications. GE Healthcare has no responsibility to Customer for cryogen boil-off rates subsequent to expiration or termination of the applicable MR system warranty, unless Customer elects to receive magnet maintenance and cryogen service under a separate agreement with GE Healthcare.

<u>For PET and PET/Cyclotron Systems Only</u>: For PET Cyclotron/Chemistry systems, any target or gas processing system purchased with the system must be installed with the original system prior to system checkout. Installation after this time will require a separate quotation by GE Healthcare and is billable to Customer at GE Healthcare's then-current rates. Further, any system storage fees associated with this order are solely the responsibility of Customer. PET Cyclotron/Chemistry systems are sold for

use in generating radiotracers for diagnostic imaging applications only. GE Healthcare does not sell or intend such systems or any part(s) thereof for use in radiation therapy.

<u>For PET/CT and PET Radiopharmacy Sites Only:</u> Customer will provide a site and surroundings suitable for installation and operation of such a systems using and/or producing radiation. Further, Customer will be responsible for obtaining all required federal, state, and local licenses and permits for radioactive sealed sources and radioisotopes used with such system. If permitted under applicable licensing requirements, GE Healthcare representatives will work under Customer's license and supervision when handling any radioactive substance for which a license is required, or Customer will provide such handling itself under an appropriate license. Customer will provide all radioactive sources and radioisotopes for calibration and performance checks of such system. Customer acknowledges that such systems utilize radioactive materials. As with all systems utilizing radioactive materials, hazards exist creating possible physical danger to persons in the vicinity.

<u>For iCenter and iLing Only</u>: GE Healthcare will provide iCenter and/or iLing information management Services at no additional charge during the term of the applicable product warranty, subject to then-applicable terms and conditions for such services.

For Healthcare IT Products Only:

- a. Payment. Unless specified separately in the Quotation, fees for non-GE Healthcare software and hardware shall be due one hundred percent (100%) on delivery of the applicable software or hardware.
- b. Audit Rights. Upon forty-five (45) days notice GE Healthcare may audit Customer's use of the software. Customer agrees to cooperate with GE Healthcare's audit and to provide reasonable assistance and access to information. If the audit uncovers underpaid or unpaid fees owe to GE Healthcare, Customer agrees to pay those fees and GE Healthcare's costs incurred in conducting the audit within thirty (30) days of written notification of the amounts owed. If Customer does not pay the amounts owed, GE Healthcare may terminate Customer's license to use the applicable software. Customer agrees to permit GE Healthcare to obtain certain reasonable information regarding the users and other use information regarding the software. All of such information shall be treated as confidential information, shall be used solely for the purposes of technical support and auditing the use of the software, and shall not be disclosed to any third party (other than third-party vendors of software licensed to Customer under this Agreement) without Customer's consent.



GE Healthcare General Terms and Conditions

GE Healthcare

References herein to "Products" and "Services" mean the Products (including equipment and software) and Services identified on the applicable GE Healthcare Quotation ("Quotation").

General Terms

- 1.1. Confidentiality. Each party will treat the terms of this Agreement and the other party's written, proprietary business information as confidential if marked as confidential or proprietary. Customer will treat GE Healthcare (and GE Healthcare's third party vendors') software and technical information as confidential information whether or not marked as confidential and shall not use or disclose to any third parties any such confidential information except as specifically permitted in this Agreement or as required by law (with reasonable prior notice to GE Healthcare). The receiving party shall have no obligations with respect to any information which (i) is or becomes within the public domain through no act of the receiving party in breach of this Agreement, (ii) was in the possession of the receiving party prior to its disclosure or transfer and the receiving party can so prove, (iii) is independently developed by the receiving party and the receiving party can so prove, or (iv) is received from another source without any restriction on use or disclosure.
- 1.2. Governing Law. The law of the state where the Product is installed or the Service is provided will govern this Agreement.
- 1.3. <u>Force Majeure</u>. Neither party is liable for delays or failures in performance (other than payment obligations) under this Agreement due to a cause beyond its reasonable control. In the event of such delay, the time for performance shall be extended as reasonably necessary to enable performance.
- 1.4. Assignment; Use of Subcontractors. Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that either party may transfer and assign this Agreement without the other party's consent to any person or entity (except to a GE Healthcare competitor) that is an affiliate of such party or that acquires substantially all of the stock or assets of such party's applicable business if any such assignees agree, in writing, to be bound by the terms of this Agreement. Subject to such limitation, this Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns. GE Healthcare may hire subcontractors to perform work under this Agreement, provided that GE Healthcare will at all times remain responsible for the performance of its obligations and duties under this Agreement.
- 1.5. <u>Amendment; Waiver; Survival</u>. This Agreement may be amended only in writing signed by both parties. Any failure to enforce any provision of this Agreement is not a waiver of that provision or of either party's right to later enforce each and every provision. The terms of this Agreement that by their nature are intended to survive its expiration (such as the confidentiality provisions included herein) will continue in full force and effect after its expiration.
- 1.6. <u>Termination</u>. If either party materially breaches this Agreement and the other party seeks to terminate this Agreement for such breach, such other party shall notify the breaching party in writing, setting out the breach, and the breaching party will have sixty (60) days following receipt of such notice to remedy the breach. If the breaching party fails to remedy the breach during that period, the other party may, subject to the terms of Section 1.4.5 of the GE Healthcare Product Terms and Conditions, terminate this Agreement by written notice to the breaching party. For the avoidance of doubt, this Agreement is not terminable for convenience and may only be terminated in accordance with this Agreement. If GE Healthcare determines in good faith at any time that there are legal or regulatory compliance and/or material credit issues with this Agreement, if any, GE Healthcare may terminate this Agreement (including warranty services hereunder) immediately upon written notice to Customer.

2. Compliance

- 2.1. Generally. This Agreement is subject to (i) GE Healthcare's on-going credit review and approval and (ii) GE Healthcare's on-going determination that Customer and this Agreement comply with all applicable laws and regulations, including those relating to workplace safety, FDA matters, Federal Healthcare Program Anti-kickback compliance, export/import control and money laundering prevention. CUSTOMER ACKNOWLEDGES THAT THE PRODUCTS ARE OR MAY BE SUBJECT TO REGULATION BY THE FDA AND OTHER FEDERAL OR STATE AGENCIES. CUSTOMER SHALL NOT USE OR PERMIT THE PRODUCTS TO BE USED IN ANY MANNER THAT DOES NOT COMPLY WITH APPLICABLE FDA OR OTHER REGULATIONS OR FOR ANY NON-MEDICAL, ENTERTAINMENT, OR AMUSEMENT PURPOSES. Further, Customer represents that it is purchasing the Products for its own use consistent with the terms of this Agreement and that it does not intend to re-sell the Products to any other party or to export the Products outside the country to which GE Healthcare delivers the Products.
- 2.2. <u>Cost Reporting.</u> Customer represents and warrants that it shall comply with (a) the applicable requirements of the Discount Statutory Exception, 42 U.S.C. 1320a-7b(b)(3)(A), and the Discount Safe Harbor, 42 C.F.R. § 1001.952(h), with respect to any discounts Customer may receive under this Agreement and (b) the Warranties Safe Harbor, 42 C.F.R. § 1001.952(g), with respect to any price reductions of an item (including a free item) which were obtained as part of a warranty under this Agreement. Customer agrees that, if Customer is required to report its costs on a cost report, then (i) the discount must be based on purchases of the same good bought within a fiscal year; (ii) Customer must claim the benefit in the fiscal year in which the discount is earned or in the following year; (iii) Customer must fully and accurately report the discount in the applicable cost report; and (iv) Customer must provide, upon request, certain information required to be provided to the Customer by GE Healthcare as a seller or offeror, as appropriate. If Customer is an individual or entity in whose name a claim or request for payment is submitted for the discounted items, the discount must be made at the time of the sale of the good; and the Customer must provide, upon request, certain information required to be provided to the Customer by GE Healthcare as a seller or offeror, as appropriate. GE

Healthcare agrees to comply with the applicable requirements for sellers or offerors under the Discount Safe Harbor, as appropriate.

- 2.3. <u>Site Access Control and Network Security</u>. Customer shall be solely responsible for establishing and maintaining security, virus protection, backup and disaster recovery plans for any data, images, software or equipment. GE Healthcare's Services do not include recovery of lost data or images. Customer shall comply with all applicable laws and regulations related to site access control.
- 2.4. <u>Environmental Health and Safety</u>. Customer shall provide and maintain a suitable, safe and hazard-free location and environment for the GE Healthcare Products and Services in material compliance with any written requirements provided by GE Healthcare, perform GE Healthcare recommended routine maintenance and operator adjustments, and ensure that any non-GE Healthcare provided Service is performed by, and GE Healthcare Products are used by, qualified personnel in accordance with applicable user documentation. GE Healthcare shall have no obligation to perform Services until Customer has complied with its obligations under this Section.
- 2.5. <u>GE Healthcare-Supplied Parts.</u> GE Healthcare can make no assurances that Product performance will not be affected by the use of non-GE Healthcare-supplied parts. In some instances, use of non-GE Healthcare-supplied parts may affect Product performance or functionality.
- 2.6. <u>Training</u>. Any Product training identified in the Quotation shall be in accordance with GE Healthcare's then-current training program offerings and terms. Unless otherwise stated in the catalog description, training must be completed within twelve (12) months after (i) the date of Product delivery for training purchased with Products and (ii) the start date for Services for training purchased with Services. If training is not completed within the applicable time period, GE Healthcare's obligation to provide the training will expire without refund.
- 2.7. <u>Medical Diagnosis and Treatment</u>. All clinical and medical treatment and diagnostic decisions are the responsibility of Customer and its professional healthcare providers.

3. Disputes; Liability; and Indemnity

- 3.1. <u>Waiver of Jury Trial</u>. EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A JURY TRIAL IN CONNECTION WITH ANY DISPUTE ARISING UNDER THIS AGREEMENT.
- 3.2. <u>Limitation of Liability</u>. GE HEALTHCARE'S (AND ITS REPRESENTATIVES') LIABILITY UNDER THIS AGREEMENT, REGARDLESS OF THE FORM OF ACTION, SHALL NOT EXCEED: (A) FOR PRODUCTS OR SERVICES OTHER THAN SERVICES UNDER AN ANNUAL SERVICE CONTRACT, THE PRICE FOR THE PRODUCT OR SERVICE THAT IS THE BASIS FOR THE CLAIM; OR (B) FOR ANNUAL SERVICE CONTRACTS, THE ANNUAL CONTRACT PRICE FOR THE SERVICE THAT IS THE BASIS FOR THE CLAIM. NEITHER CUSTOMER NOR GE HEALTHCARE (NOR THEIR RESPECTIVE REPRESENTATIVES) SHALL BE LIABLE TO THE OTHER PARTY UNDER THIS AGREEMENT (OR OTHERWISE IN CONNECTION WITH THE PRODUCTS AND SERVICES) FOR ANY INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR LOSS OF PROFITS, REVENUE, TIME, OPPORTUNITY OR DATA, WHETHER IN AN ACTION IN CONTRACT, TORT, PRODUCT LIABILITY, STATUTE, EQUITY OR OTHERWISE. THE LIMITATION OF LIABILITY AND EXCLUSION OF DAMAGES SHALL APPLY EVEN IF THE LIMITED REMEDIES FAIL OF THEIR ESSENTIAL PURPOSE.
- 3.3. IP Indemnification. GE Healthcare will defend, indemnify and hold harmless Customer from any third party claims for infringement of intellectual property rights arising from Customer's use of GE Healthcare manufactured equipment and/or GE Healthcare proprietary software listed in the Quotation in accordance with their specifications and within the license scope granted in this Agreement. If any such claim materially interferes with Customer's use of such equipment and/or software, GE Healthcare shall, at its option: (i) substitute functionally equivalent non-infringing products; (ii) modify the infringing Product so that it no longer infringes but remains functionally equivalent; (iii) obtain for Customer at GE Healthcare's expense the right to continue to use the infringing Product; or (iv) if the foregoing are not commercially reasonable, refund to Customer the purchase price, as depreciated (based on five (5) year straight-line depreciation), for the infringing Product. Any such claims arising from Customer's use of such infringing Product after GE Healthcare has notified Customer to discontinue use of such infringing Product and offered one of the remedies set forth in clauses (i) through (iv) above are the sole responsibility of Customer. This Section represents Customer's sole and exclusive remedy (and GE Healthcare's sole and exclusive liability) regarding any infringement claim associated with such infringing Product. The above indemnification obligation is conditional upon Customer providing GE Healthcare prompt written notice of the infringement claim after receiving notice of such claim, allowing GE Healthcare to control the defense of such claim, and reasonably cooperating with GE Healthcare in such defense. Notwithstanding any other provision in this Agreement, GE Healthcare shall not have any obligation to Customer hereunder for infringement claims based on or resulting from: (a) use of such infringing Product in combination with any computer software, tools, hardware, equipment, materials, or services, not furnished or authorized in writing for use by GE Healthcare; (b) use of such infringing Product in a manner or environment or for any purpose for which GE Healthcare did not design or license it, or in violation of GE Healthcare's use instructions; or (c) any modification of such infringing Product by Customer or any third party. GE Healthcare shall not be responsible for any compromise or settlement or claim made by Customer without GE Healthcare's written consent. This indemnification obligation is expressly limited to the GE Healthcare manufactured equipment and/or GE Healthcare proprietary software listed in the Quotation.

4. Payment and Finance

- 4.1. Generally. The payment and billing terms for the Product(s) and/or Service(s) are stated in the Quotation.
- 4.2. <u>Affiliate Billing</u>. If Customer's order includes Products manufactured by more than one GE Healthcare affiliated company, each affiliated company may invoice Customer separately for the portion of the total price under the Quotation attributable to its Products, under the same payment terms specified in the Quotation. There shall be no additional fees or charges to Customer for such separate invoicing.
- 4.3. <u>Late Payment</u>. Failure to make timely payment is a material breach of this Agreement, for which (in addition to other available remedies) GE Healthcare may suspend performance under any or all GE Healthcare agreements until all past due amounts are brought current. If GE Healthcare so suspends, GE Healthcare will not be responsible for the completion of planned maintenance due to be performed during the suspension period and any product downtime will not be included in the calculation of any uptime commitment. Interest shall accrue on past-due amounts at a rate equal to the lesser of one-and-one-half percent (1.5%) per month or the maximum rate permitted by applicable law. Customer will reimburse GE Healthcare for reasonable costs (including attorneys' fees) relating to collection of past due amounts. Any credits that may be due to Customer under an agreement may be applied first to any outstanding balance. If Customer has a good faith dispute

regarding payment for a particular Product (or subsystem thereof) or Service, such dispute shall not entitle Customer to withhold payment for any other Product (or subsystem thereof) or Service provided by GE Healthcare. GE Healthcare may revoke credit extended to Customer because of Customer's failure to pay for any Products or Services when due, and in such event all subsequent shipments and Services shall be paid for on receipt.

4.4. <u>Taxes</u>. Prices do not include sales, use, gross receipts, excise, valued-added, services, or any similar transaction or consumption taxes ("Taxes"). Customer shall be responsible for the payment of any such Taxes to GE Healthcare unless it otherwise timely provides GE Healthcare with a valid exemption certificate or direct pay permit. In the event GE Healthcare is assessed Taxes, interest or penalty by any taxing authority, Customer shall reimburse GE Healthcare for any such Taxes, including any interest or penalty assessed thereon. Each party is responsible for any personal property or real estate taxes on property that the party owns or leases, for franchise and privilege taxes on its business, and for taxes based on its net income or gross receipts.



GE Healthcare Product Terms and Conditions

GE Healthcare

References herein to "Products" and "Services" mean the Products (including equipment and software) and Services identified on the applicable GE Healthcare Quotation ("Quotation"). References herein to "Healthcare IT Products" are (i) those software products identified in the Quotation as a "Centricity" product, any third party software licensed for use in connection with the Centricity software, all hardware used to operate the Centricity or the third party software, and services provided with respect to the implementation, installation or support and maintenance of the Centricity or the third party software, and/or (ii) any software, product or service that is included in a Quotation which Quotation is designated as an "Healthcare IT Quotation".

Commercial Logistics

1.1. Order Cancellation and Modification.

- 1.1.1. Cancellation and Payments. Except for Healthcare IT Products, if Customer cancels an order without GE Healthcare's prior written consent, Customer will pay a cancellation charge of fifteen percent (15%) of the price of the Products ordered. GE Healthcare will retain as a credit any payments received up to the amount of the cancellation charge. If Customer cancels an order for Products for which GE Healthcare has provided site evaluation services, Customer will also pay GE Healthcare reasonable charges for such services performed prior to cancellation. If applicable for the order, Customer will pay all progress payments (other than the final payment) prior to final Product calibration, and GE Healthcare may, at its option, delay final calibration until required progress payments are received. If Customer fails to schedule a delivery date with GE Healthcare within six (6) months after order entry, GE Healthcare may cancel Customer's order upon written notice to Customer.
- 1.1.2. Order Modifications. No modifications may be made to an order without GE Healthcare's prior written consent. The Product configuration listed in the Quotation is based upon information furnished to GE Healthcare by Customer, and Customer is responsible to provide and pay for modifications, if any, to the configuration due to inaccuracies or incompleteness of the information furnished to GE Healthcare by Customer, changes in Customer's needs or requirements, or for other reasons attributable to Customer.
- 1.2. Site Preparation. If applicable, Customer will be responsible, at its sole expense, for evaluating and preparing the site where the Products will be installed in accordance with GE Healthcare's site preparation requirements and applicable laws. Customer must provide GE Healthcare with prompt written notice if Customer is unable to prepare the site before the mutually agreed installation date. Upon receipt of such notice, GE Healthcare will reschedule the installation to a mutually agreed date. Customer shall be liable for any costs or expenses GE Healthcare or its representatives incur resulting from Customer's failure to provide GE Healthcare with timely notice of Customer's failure to properly prepare the site. GE Healthcare may, in its discretion, delay delivery or installation if GE Healthcare determines that the site has not been properly prepared or there are any other impediments to installation; provided that GE Healthcare gives Customer written notice of such delay stating the reasons therefor. If GE Healthcare provides site evaluation services, such services are intended only to assist Customer in fulfilling Customer's responsibility to ensure that the site complies with GE Healthcare's applicable site preparation requirements.

1.3. Transportation, Title and Risk of Loss; Delivery; Returns.

- 1.3.1. <u>Transportation, Title and Risk of Loss</u>. Unless otherwise indicated in the Quotation, shipping terms are FOB Destination. Title and risk of loss to equipment passes to Customer upon delivery to Customer's designated delivery location. Software is licensed to Customer; no title to or other ownership interest in such software passes to Customer.
- 1.3.2. <u>Delivery.</u> When feasible, GE Healthcare reserves the right to make delivery in installments. All such installments shall be separately invoiced and paid for when due, without regard to subsequent deliveries. At the time of such delivery, Customer will pay GE Healthcare for any amounts due upon delivery. Delivery dates are approximate. For GE Healthcare software or documentation, delivery means the first to occur of: (i) communication to Customer through electronic means, that allows Customer to take possession of the first copy or product master, or (ii) delivery to Customer's designated delivery location.
- 1.3.3. <u>Product Returns.</u> Customer shall not have any right to return Products for a refund after delivery except for products shipped in error that are different from the Products listed in the Quotation.
- 1.4. Installation and Certification. GE Healthcare will provide product assembly, installation and calibration, as required, at no additional charge, except for items excluded herein. GE Healthcare installation Services provided under the Quotation will be performed in accordance with applicable GE Healthcare installation guides and/or project plans. Customer will review the applicable GE Healthcare installation guides, and/or project plans, and perform Customer's obligations as set forth in those materials. Upon completion of assembly, installation and calibration, and prior to turnover of the Products to Customer for clinical use, as applicable, GE Healthcare will perform prescribed tests using its own performance specifications, instruments and procedures to verify that the Products meet GE Healthcare's applicable performance specifications.

1.4.1. Customer-Supplied Items.

- Customer will install necessary system cable and assemble any necessary equipment or hardware not provided by GE
 Healthcare, unless agreed otherwise in writing by the parties.
- For Products that will be operated on or in connection with Customer supplied hardware or software, Customer is responsible

- for ensuring that such hardware and software conform to GE Healthcare's minimum hardware and software requirements as made available to Customer.
- Unless GE Healthcare has agreed in writing to maintain responsibility for an applicable service, Customer will be responsible for
 enabling the connectivity and interoperability between Customer-supplied hardware or software or other systems or devices
 and the Product, including, without limitation, procuring and installing any modifications, interfaces or upgrades consistent with
 GE Healthcare's written specifications.
- Unless otherwise agreed in writing by GE Healthcare, Customer is solely responsible for the performance of and payment for any
 applicable rigging and/or facility costs. GE Healthcare will not install accessory items unless otherwise agreed in writing by GE
 Healthcare.
- If applicable for the Product, electrical wiring and outlets, computer network infrastructure, conduit, cabinetry modification, wall mounts, ventilation and any other site preparation are not included in the purchase price and are the responsibility of Customer, unless otherwise agreed in writing by GE Healthcare.
- 1.4.2. <u>Network.</u> Unless Customer has elected to purchase network preparation and certification Services from GE Healthcare as set forth in the Quotation, Customer is solely responsible for ensuring that Customer's network is adequate for the proper operation and performance of the Products and otherwise meets GE Healthcare's written network configuration requirements.
- 1.4.3. <u>License, Permits, and Approvals</u>. Customer shall obtain and maintain all licenses, permits and other approvals necessary for installation, use, and disposal/recycling of the Products provided under this Agreement, including, but not limited to, any government licenses required to use radioactive sources for Products that require the use of such sources. GE Healthcare will ship such sources to Customer only after Customer provides GE Healthcare with satisfactory evidence that Customer has obtained all required licenses for such sources In addition, Customer will provide all radioactive sources for colibration and performance checks of Products that require the use of such sources. GE Healthcare will file any required Federal and State reports relating to its installation activities. GE Healthcare will not install, test, certify or provide its own software license or warranty for Products that are not listed in its on-line catalog or price pages at the time of sale (such Products are normally identified by NL or NW series numbers), unless otherwise agreed in writing by GE Healthcare.
- 1.4.4. <u>Non-GE Healthcare Labor</u>. If local labor conditions make it impractical to, or GE Healthcare is directed not to, use GE Healthcare's employees or pre-qualified contractors for the installation, all work will be performed by Customer's laborers or outside labor at Customer's expense; provided that GE Healthcare will, at Customer's request, furnish guidance for installation. GE Healthcare is not responsible for the quality or adequacy of any work performed by any party other than GE Healthcare or its pre-qualified contractors.
- 1.4.5. Non-GE Healthcare Installation. For Products that GE Healthcare is obligated to install under the terms of this Agreement, if GE Healthcare delivers the Product but fails to perform its installation obligations, then in such event Customer shall nevertheless be obligated to pay GE Healthcare an amount equal to (a) the Product purchase price set forth in the Quotation, if the Product purchase price and the installation Services price are shown as separate line items in the Quotation, or (b) if the Product purchase price and installation Services price are not shown as separate line items in the Quotation, then the Product purchase price less the fair market value of the applicable installation Services, taking into account the type of Product and level of installation required ("Installation Service FMV"). An independent third party shall determine the Installation Service FMV. Notwithstanding any other provision of this Agreement to the contrary, either the discharge of Customer's obligation to pay for installation Services shown as a separate line item(s) in the Quotation or the deduction of the Installation Service FMV, as applicable, shall be Customer's sole and exclusive remedy (and GE Healthcare's sole and exclusive liability) in the event GE Healthcare fails to perform its installation obligations under this Agreement.
- 1.5. Acceptance. Unless expressly provided otherwise in this Agreement, Customer shall be deemed to have accepted a Product delivered by GE Healthcare under this Agreement on the earlier of: (i) if GE Healthcare installs the Product, five (5) days after GE Healthcare notifies Customer that it has completed assembly and the Product is operating substantially in accordance with GE Healthcare's published performance specifications; (ii) if GE Healthcare does not install the Product, five (5) days after delivery of the Product to Customer; or (iii) the date Customer first uses the Product for patient use.
- 1.6. <u>Warranties</u>. Product warranties (if applicable) are set forth in the GE Healthcare warranty forms delivered with the Quotation. GE Healthcare may use refurbished parts in new Products as long as it uses the same quality control procedures and warranties as for new Products. Any part for which GE Healthcare has supplied a replacement shall become GE Healthcare property.
- 1.7. <u>Data Access</u>. If applicable, Customer shall permit GE Healthcare to connect to the Products, or to otherwise access Product performance data through a Customer-furnished telephone line or Broadband connection. The data collected by GE Healthcare will be used, during and after the term of this Agreement, in accordance with all applicable laws and regulations and in a manner that will maintain confidentiality.

2. Software License

2.1. <u>License Grant.</u> GE Healthcare grants to Customer a non-exclusive, non-transferable license to use for Customer's internal business purposes the GE Healthcare software, third-party software and Documentation at the location (or, for mobile systems, in the specific vehicle) identified in the Quotation, subject to the license scope and other restrictions set forth in this Agreement. "Documentation" means the GE Healthcare user manuals, on-line help functions, technical specifications and user instructions regarding the operation, installation and use of the software as made available by GE Healthcare to Customer. Customer may only use third-party software provided by GE Healthcare together with the GE Healthcare software and will comply with all third-party software license terms included in any click or shrink wrap license or of which GE Healthcare otherwise makes Customer aware. To the extent permitted by applicable law, licensors of third-party software shall be third-party beneficiaries of this Agreement with respect to third-party software sublicensed under this Agreement. Customer may permit its employees, agents, independent contractors and healthcare providers with privileges at Customer's facilities to use the software and Documentation; provided, however, that Customer shall be responsible for any acts of such third parties that are inconsistent

with this Agreement. Notwithstanding the foregoing, independent contractors that supply products comparable to the software shall be provided access to the software only with GE Healthcare's prior written consent and subject to any conditions GE Healthcare deems appropriate to protect its confidential and proprietary information.

- 2.2. Additional License Terms. Without GE Healthcare's prior written consent, Customer may not: (i) copy, sublicense, distribute, rent, lease, loan, resell, modify or translate the software or create derivative works based thereon, except that to the extent applicable, the software may be configured as specifically permitted in the Documentation; (ii) directly or indirectly decompile, disassemble, reverse engineer or otherwise attempt to learn the source code, structure, algorithms or ideas underlying the software; (iii) provide service bureau, time share or subscription services based on the software; (iv) remove, obscure or modify any markings, labels or any notice of the proprietary rights, including copyright, patent and trademark notices of GE Healthcare or its licensors; (v) electronically transfer the software outside Customer's intranet or network dedicated for the software, unless otherwise authorized in writing by GE Healthcare; or (vi) publicly release the results of any testing or benchmarking of the software without the prior written consent of GE Healthcare. Customer may transfer authorized copies of the software, and Documentation to a party that purchases or otherwise acquires the equipment and accepts any applicable license terms, except for software and Documentation that are (a) not a part of the base system standard operating software or Documentation for the equipment and (b) generally provided by GE Healthcare to its customers for a separate fee or charge. Advanced service software is subject to a separate fee and eligibility criteria and licensed under a separate agreement with GE Healthcare.
- 2.3. <u>Backups</u>. Customer may make a reasonable number of copies of the software in machine-readable form solely for backup, training, testing or archival purposes, so long as applicable license fees are paid. Customer shall reproduce on any such copy the copyright notice and any other proprietary legends that were on the original copy. GE Healthcare and its licensors, as applicable, retain all ownership and intellectual property rights to the software and Documentation. If Customer acquires any rights to the software or Documentation, Customer hereby assigns all of those rights to GE Healthcare or its licensors, as applicable. No license rights are granted (whether by implied license or otherwise), to Customer, except as specifically provided in this Section.
- 2.4. <u>Remedies</u>. Customer agrees that a violation of GE Healthcare's license, confidentiality or intellectual property rights will cause irreparable harm to GE Healthcare for which the award of money damages alone are inadequate. In the event of any breach of this provision, GE Healthcare shall be entitled to seek injunctive relief in addition to immediately terminating the license granted herein and requiring that Customer cease use of the software and return all copies of stand-alone software in any media in addition to seeking any other legal or equitable remedies available to GE Healthcare. This paragraph shall survive the termination of this Agreement.

3. Payment and Finance

- 3.1. <u>Security Interest; Upgrade Pricing.</u> Customer grants GE Healthcare a purchase money security interest in all items of hardware or equipment listed in the Quotation until full payment is received, and Customer shall perform all acts and execute all documents as may be necessary to perfect GE Healthcare's security interest. Except for Healthcare IT Products, prices for upgrades and revisions assume that Customer returns the replaced component and transfers title to GE Healthcare at no charge to GE Healthcare. If, after Product delivery, Customer does not make any payments for the Products within forty-five (45) days after such payments are due, GE Healthcare may, upon ten (10) days prior written notice to Customer, either (a) enter upon Customer's site and remove the Products or (b) temporarily disable the Products so that they are not operational.
- 3.2. <u>Leases</u>. If Customer is acquiring use of Products through an equipment lease (a "Lease") with an equipment lessor (a "Lessor"), certain provisions of this Agreement (including, but not limited to, terms related to payment, title transfer, warranties, and software licenses) may be modified as agreed to in writing between GE Healthcare, the applicable Lessor, and/or Customer, as the case may be. Acceptance of the equipment as between GE Healthcare and Lessor will be defined by this Agreement; acceptance of the equipment as between Lessor and Customer will be defined by the lease agreement. Notwithstanding the foregoing, if the Lessor does not comply with the terms of this Agreement, Customer shall continue to be responsible for the payment obligations hereunder.

4. Product Specific Terms

- 4.1. MUSE CV Information Technology Professional Services (ITPS). MUSE CV Product ITPS shall be performed within six (6) months of the date Customer orders the Services. Without limiting the foregoing, Customer agrees that, if the Services have not been performed within one (1) year of the date Customer orders the Services for reasons other than GE Healthcare's failure to perform, GE Healthcare shall be relieved of its obligation to perform the Services and the Customer shall not be entitled to a refund for such unperformed Services. ITPS Services include clinical applications training, project management, HL7/HIS systems integration, database conversion, and network design and integration (NDRI)
- 4.2. <u>Pre-Owned Products</u>. Products identified as pre-owned/refurbished/remanufactured Products have been previously owned and used; they are not new. When delivered to Customer, such Products may have received mechanical, electrical, and/or cosmetic reconditioning, as necessary, and will meet their original specifications. Since pre-owned Products may be offered simultaneously to several customers, their sale to Customer is subject to their continued availability at the time Customer offers to purchase such Products. If the pre-owned Products are no longer available, (i) GE Healthcare will attempt to identify other pre-owned Products in its inventory that meet Customer's needs, and (ii) if substitute pre-owned Products are not acceptable to Customer, GE Healthcare will cancel the order and refund any deposit Customer has paid for such Products.
- 4.3. <u>CT and X-Ray Products</u>. Certain Products that use x-ray or image intensifier tubes have been designed to recognize GE Healthcare-supplied tubes and report to the user the presence of a non-GE Healthcare-supplied tube. This will permit the user to make any adjustments to Product use that the user deems appropriate. Use of the Products with non-GE Healthcare-supplied tubes is always at the user's discretion; however, Customer acknowledges that advanced scanner functionality may be impaired or disabled by the use of non-GE Healthcare-supplied tubes. GE Healthcare assumes no liability for the use of non-GE-Healthcare-supplied tubes and disclaims any responsibility for any effect such tubes may have on Product performance.



GE Healthcare

GE Healthcare Additional Terms and Conditions: Uptime Commitment

This Uptime Commitment incorporates GE Healthcare's General Terms and Conditions and GE Healthcare's Product Terms and Conditions and will apply to eligible diagnostic imaging systems covered by the Quotation, as identified in the Quotation ("Eligible Systems").

- 1. Scope. GE Healthcare will provide Customer with expanded warranty protection for Eligible Systems in consideration of Customer's commitment to provide a broadband network connection to enable GE Healthcare to better provide warranty service for the Eligible Systems during the warranty period. The following provisions will apply only to Eligible Systems and only during the warranty period.
- 2. Eligibility. To be eligible for this expanded warranty protection, Customer must: (a) establish (if not previously established) and maintain a broadband network connection at Customer's site that connects to the Eligible System, which broadband connection meets GE Healthcare's minimum specifications, (b) provide GE Healthcare with access to the Eligible System through Customer's broadband network connection and maintain security for Customer's broadband network connection in accordance with appropriate industry best practices, (c) provide necessary support to maintain such broadband network connection, including designation of a primary Customer contact person, (d) provide GE Healthcare with at least two (2) business days advance notice of any planned changes to Customer's network that may impact such broadband connection and with notice of any unplanned changes (e.g., power outages, computer viruses, system crashes) to Customer's network that may impact such broadband connection within two (2) business days after the occurrence of the unplanned changes, (e) reasonably cooperate with GE Healthcare in maintaining such broadband connection during all such planned and unplanned changes, and (f) use reasonable efforts to ensure that Customer's connection to the Internet and LAN systems operate at a maximum of 75% of capacity and have an uptime rate of at least 98%.
- 3. Uptime Commitment. If Customer performs these responsibilities, GE Healthcare will provide Customer, at no additional charge and in addition to other remedies available under GE Healthcare's warranty, an uptime commitment of 97% (95% for all covered nuclear imaging systems and all covered X-ray systems except digital mammography, digital radiographic and vascular X-ray systems), and uptime remedies, as described below.
- 4. Definitions. "Uptime Commitment" means GE Healthcare's commitment on Eligible System uptime during the warranty period, as defined below. "Uptime Remedy" is, in addition to the other remedies specified in the warranty, Customer's sole and exclusive remedy if GE Healthcare fails to meet any Uptime Commitment over a 26-week measurement period during the warranty period. Should the Eligible System fail to achieve the Uptime Commitment as calculated by the Uptime Commitment Calculation, GE Healthcare will provide an extension of Customer's service agreement with GE Healthcare for the Eligible System (or, if Customer has not entered into a service agreement with GE Healthcare, the warranty period for the Eligible System) at no additional charge, as follows:

% < Uptime Commitment	Extension
0	0 weeks
0.1 - 3.0	1 week
3.1 - 8.0	2 weeks
8.1 - 13.0	4 weeks
> 13.0	6 weeks

"Uptime Commitment Calculation" means the calculation used to determine achievement of the Uptime Commitment, as follows: The basis for each measurement period is GE Healthcare's standard warranty service coverage hours of <u>A</u> hours per day, <u>B</u> days per week for 26 weeks, less C hours spent on planned maintenance ("PM") during that interval:

Hours1 = A hours per day X B days per week X 26 weeks Hours2 = Hours1 - C hours for planned maintenance

Required in-service hours at Customer's % commitment: Hours3 = Hours2 X Customer's %

5. Eligible System. An Eligible System will be considered inoperable and out of service under the Uptime Commitment if, due to GE Healthcare's design, manufacturing, material, or service or maintenance performance failure, the Eligible System is unavailable for scanning patients and diagnosing images on the Eligible System display console or operator's console. Peripheral equipment such as remote consoles, magnetic tape drives, hard copy devices, and multi-format and laser cameras are excluded from the terms of the Uptime Commitment. Repair and adjustments required for anything other than Eligible System failure, and damage or inoperability due to any cause other than GE Healthcare's design, manufacturing, material, or service or maintenance performance failure, will be excluded from the Uptime Commitment Calculation, including without limitation damage through misuse, operator error, inadequate environmental or air conditioning protection, power failure, and acts of God. PM time will not be included in the calculation of downtime. If GE Healthcare's responding representative agrees the Eligible System is inoperable due to GE Healthcare's design, manufacturing, material, or service or maintenance performance failure, the Eligible System will be considered out of service from the time the request for service was received by GE Healthcare until the Eligible System is again turned over to Customer for operation. If Customer fails to give GE Healthcare immediate and unencumbered access to the Eligible System or continues to obtain scans after notifying GE Healthcare of any Eligible System failure, the Eligible System will be considered to be in service.



GE Healthcare

GE Healthcare Additional Terms and Conditions: Healthcare IT

References herein to "Products" and "Services" mean the Products (including hardware and software) and Services purchased by Customer as identified on the applicable GE Healthcare Quotation ("Quotation"). References herein to "Healthcare IT Products" are (i) those software products identified in the Quotation as a "Centricity" product, any third party software licensed for use in connection with the Centricity software, all hardware used to operate the Centricity or the third party software, and services provided with respect to the implementation, installation or support and maintenance of the Centricity or the third party software, and/or (ii) any software, product or service that is included in a Quotation which Quotation is designated as an "Healthcare IT Quotation".

These Additional Terms and Conditions incorporate the GE Healthcare General Terms and Conditions as well as the GE Healthcare Product Terms and Conditions and will apply only to the license, purchase and use of Healthcare IT Products.

- 1. Healthcare IT Product Specific Terms. The following terms apply only to the purchase of Healthcare IT Products.
- 1.1. Statement of Work (SOW). Following the effective date of this Agreement, the parties may enter into a written statement of work ("SOW") signed by the parties that describe the professional services to be provided by pursuant to the quotation, which may include, among other things, an installation and implementation project work plan, identification of installation and implementation services, and other related professional services. GE Healthcare shall perform the professional services and provide any deliverables described in any such SOW and shall use commercially reasonable efforts to do so according to any delivery schedule in the SOW. GE Healthcare is responsible for the assignment of personnel to perform all services and may make any change in staffing it deems necessary provided that such change does not compromise the level of expertise required to complete the applicable SOW. Each SOW may include descriptions of the following: (i) professional services to be performed; (ii) deliverables; (iii) Customer's additional responsibilities; (iv) project work scope, (v) estimated performance schedule and applicable milestones; (vi) Customer's site and any site preparation requirements; (vii) network, hardware or other environmental or infrastructure requirements; (viii) preliminary implementation plans; or (ix) key assumptions. The terms and conditions of this Agreement shall prevail over those of the SOW. A SOW may only be modified in writing signed by authorized representatives of both parties and must be made pursuant to mutually agreed change control procedures. Changes to a SOW may require a change in fees reflecting the change in scope and/or change in schedule of delivery of the professional services or deliverables and/or change in Customer's responsibilities. From time to time during the term of this Agreement, the parties may enter into additional SOWs relating to services purchased by Customer under Change Orders to this Agreement. Each such additional SOW shall constitute a separate and indepen
- 1.2. Project Managers. If required by the SOW, Customer and GE Healthcare shall each designate a project manager who will be responsible for day-to-day communications regarding the subject matter of the applicable SOW. The project managers will be responsible for monitoring the schedules and progress of services pursuant to the Agreement and/or SOW and will have the authority to act for the respective parties in all aspects of the engagement. The project managers for the parties will meet in person or via conference call as necessary. The responsibilities of the project managers include to: (i) serve as the single point of contact for all departments in their organization participating in this project; (ii) administer the change-of-control procedure; (iii) participate in project status meetings; (iv) obtain and provide information, data, decisions and approvals, within seven working days of the other party's request unless GE Healthcare and Customer mutually agree to an extended response time; (v) resolve deviations from project plans that may be caused by the parties' respective organizations; (vi) help resolve project issues and escalate issues within the parties' respective organizations, as necessary; (vii) monitor and report project status on a regular basis to the respective organizations as appropriate; and (viii) provide and coordinate technical and specialist resources as necessary.
- 1.3. HITECH Certification. GE Healthcare will use diligent efforts to obtain certification under the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act") to the extent that certification standards are established for the applicable functionality included as part of GE Healthcare's EMR or Centricity Practice Solutions software licensed by Customer, including those product updates that GE Healthcare provides generally to Customer of such products as part of support and maintenance. If GE Healthcare fails to obtain certification for the applicable components within ninety (90) days after the beginning of the first Reporting Period in a Payment Year that Customer is actively seeking to demonstrate Meaningful Use, GE Healthcare will credit the standard support services fees for such software for each month during which the software is not certified (up to a maximum of 6 months) against future support fees. The foregoing is Customer's sole and exclusive remedy in the event GE Healthcare fails to obtain certification. For the avoidance of doubt, Customer's payment obligations under this Agreement are not conditioned on receipt of HITECH incentive payments, certification of the software or demonstration of meaningful use. GE Healthcare will keep Customer informed of GE Healthcare's certification status by posting such status at www.gehealthcare.com/hitech (or some other location that of which GE Healthcare may inform Customer). It is Customer's responsibility to ensure Customer meets all the requirements to qualify for the incentive payments, including "meaningful use", and to confirm that the GE Healthcare software Customer is using is certified according to HITECH criteria. GE Healthcare's obligations under this section apply only to the then-most current version of GE Healthcare's Centricity EMR or Centricity Practice Solution software products. GE Healthcare's obligations are contingent upon Customer thenreceiving and paying for support services and complying with the requirements of the GE Healthcare service policy and, if GE Healthcare so requires, upon Customer installing software fixes, patches or updates or migrating to a new or different GE Healthcare software offering, and on Customer otherwise having installed all functionality not part of the GE Healthcare software that would have been required to show Meaningful Use. All capitalized terms shall the definitions set forth in this Agreement, the HITECH Act or any applicable implementing
- 1.4. Ownership Rights. GE Healthcare shall retain ownership of all deliverables (including any intellectual property embodied in the

deliverables or related to them) and any intellectual property developed under a SOW or during the course of performing the services whether or not the services are performed by GE Healthcare alone or jointly with Customer or others. In addition, GE Healthcare shall own all improvements, enhancements and derivative works of any GE Healthcare intellectual property. Customer hereby assigns, and will cause Customer's employees and independent contractors to assign, to GE Healthcare all of Customer's rights in and to such deliverables and intellectual property. GE Healthcare grants to Customer a nonexclusive, nontransferable, license, without the right to sublicense, to use the deliverables solely for Customer's internal business purposes and subject to the limitations described in this Agreement and the relevant SOW. Customer agrees to provide reasonable assistance to GE Healthcare in obtaining and enforcing GE Healthcare's rights to such deliverables and intellectual property. GE Healthcare will acquire no rights to any of Customer's confidential information that may be included in any deliverable unless expressly agreed to otherwise by Customer.

- 1.5. <u>Software Product Testing and Acceptance</u>. Commencing on the date that GE Healthcare gives notice of installation of the GE Healthcare software (or on the date as otherwise provided for in the applicable SOW) and implementation by GE Healthcare of appropriate option and parameter selections made by Customer, Customer will have thirty (30) days to test each unit or module of the GE Healthcare software. Customer shall be deemed to have accepted GE Healthcare proprietary software the earlier of (i) Customer's written acceptance, (ii) the expiration of the test period identified in the preceding sentence without GE Healthcare receiving written notice from Customer of the existence of any errors and a reasonable description of such error(s), or (iii) the date Customer first uses the software to process actual data in the operation of Customer's business (e.g. to register a patient, to produce a bill, to record a treatment or diagnosis or to process or view a medical image). As used in this section, an "error' is the failure of the software to perform substantially in accordance with the documentation. Acceptance tests will be conducted using test data, preferably from Customer's historical operations, in a non-productive environment and according to test protocol to be mutually agreed upon by the parties. Upon discovering an error, Customer shall promptly notify GE Healthcare in writing of the error, which notice shall include a reasonable description of the error. Upon GE Healthcare's timely receipt of Customer's written notice, GE Healthcare shall promptly correct such failures identified by Customer therein. An acceptance test for amendments or alterations provided by GE Healthcare as a result of testing may be conducted by Customer for a period of not more than five [5] days after delivery of such amendment or alteration, and the test period shall be extended for this purpose. Upon the occurrence of acceptance, all payments associated with acceptance, if any, shall be due and payable.
- 1.6 <u>Software Support.</u> GE Healthcare will provide to Customer the software support services as described in the applicable GE Healthcare service policy for the GE Healthcare software and the support period as specified in the applicable quotation for which Customer has paid the applicable fees. Software that is identified on the quotation and either (i) is delivered to Customer in a third-party developer/supplier's packaging and with its labeling or (ii) for which GE Healthcare expressly indicates (either in the quotation or in the product documentation) that the software is provided with the third-party developer/supplier's software support services in lieu of GE Healthcare software support services is not covered under this Agreement unless specifically stated otherwise in the applicable quotation. GE Healthcare support services will automatically renew for another annual term upon payment of the applicable renewal support fees, unless either party provides sixty (60) days prior written notice of non-renewal. GE Healthcare may increase its charges for support and maintenance fees for each successive annual software renewal support term. In connection with any annual renewal of support services, GE Healthcare may increase its annual charges for maintenance and support by no more than CPI plus two percent (2%). CPI shall mean the U.S. City Average (December to December percent) for ALL Urban Consumers (CPI-U). If GE Healthcare announces to its customers that it will no longer offer support ("end of product life") for a product or component, then upon at least twelve (12) months' prior written notice to Customer, GE Healthcare may, at its option, remove any such item from all GE Healthcare service agreements, with an appropriate adjustment of charges, without otherwise affecting such agreements.
- Medical Diagnosis and Treatment. Customer acknowledges that: (a) the software does not make clinical, or other decisions and is not a substitute for competent, properly trained and knowledgeable staff who bring professional judgment and analysis to the information presented by the software; (b) Customer is responsible for verifying the accuracy of all patient information and determining the data necessary for Customer and Customer's users to make medical and diagnostic decisions, as well as for complying with all laws, regulations and licensina requirements applicable to Customer's delivery of healthcare services; (c) Customer is responsible for establishing and maintaining reasonable auality control procedures to ensure the accuracy of input to the software; (d) Customer and Customer's staff will consider all relevant information including information presented to Customer and Customer's staff by the software and may give whatever weight Customer and Customer's staff deem appropriate to the information produced by the software in the performance of Customer's and Customer's staff's functions; (e) any and all financial and management information produced by the software must be tested for reasonableness and accuracy before any actions are taken or reliance placed on it; (f) Customer has reviewed and will communicate to users who use and access the software any software information, which may be provided to Customer by GE Healthcare from time to time; (g) although GE Healthcare and its third-party vendors have used reasonable care in obtaining information from sources believed to be reliable, Customer acknowledges that it is Customer's obligation to be informed about any changes or developments in clinical information or guidelines that may not be reflected in the software and that the absence of an alert or warning for a given course of treatment, drug or drug combination should not be construed to indicate that the treatment, drug or drug combination is safe, appropriate or effective in any given patient; (h) Customer is solely responsible for the proper, complete and accurate submission of claims, including without limitation the determination of proper billing, diagnosis and procedure codes and the maintenance of patient medical records containing appropriate documentation of the Services billed; (i) when selecting a narrative condition or coded diagnosis or procedure, Customer must make an independent and informed judgment based upon the patient's condition and symptoms and/or a physician's submitted diagnosis, to select a code appropriate for that patient (GE Healthcare does not make any representation or warranty regarding the appropriateness of any of the narrative or codes displayed for any or all patients); (j) since it is possible that a payor's local medical review policies may be in effect prior to their receipt or update by GE Healthcare or its licensors, Customer, as a provider under Federal health care programs, assumes responsibility for the accuracy of all claims submitted for Services performed for Medicare beneficiaries. Customer shall use the Products only for clinical diagnostic purposes in the diagnosis or treatment of a disease or condition, and not for any entertainment or amusement purposes. GE Healthcare will not deliver, install, service or provide training on use of the Products if GE Healthcare discovers the Products have been or are intended to be used for non-clinical purposes

in violation of the preceding sentence.

- 1.8 <u>Return of Software</u>. Upon termination of this Agreement for any reason, Customer shall immediately return to GE Healthcare any and all software for which license grant immediately terminates.
- 2. Healthcare IT Warranty. The following warranties apply only to Healthcare IT products and are in lieu of any other standard GE Healthcare warranties.
- 2.1. Express Warranties. GE Healthcare makes the following express warranties to Customer:
 - 2.1.1. GE Healthcare warrants that its services will be performed by trained individuals in a professional, workman-like manner.
 - 2.1.2. Except as indicated otherwise below, GE Healthcare warrants that (i) GE Healthcare has the right to license or sublicense the software to Customer for the purposes and subject to the terms and conditions set forth herein, (ii) for 90 days following the warranty commencement date, the software will perform substantially in accordance with the applicable documentation, (iii) it has not inserted any disabling code (as defined herein) into the software, and (iv) it will use reasonable commercial efforts consistent with industry standards to scan for and remove any software viruses before installation of the software. As used herein, (a) "disabling code" means computer code that is designed to delete, interfere with, or disable the normal operation of the software; provided, however, that code included in the software that prohibits use outside of the license scope purchased for the software will not be deemed to be disabling code, and (b) "warranty commencement date" means the date upon which Customer first uses the software to process actual data in the operation of Customer's business (e.g., to register a patient, to produce a bill, to record a treatment or diagnosis or to process or view a medical image). The warranty period for any software or component furnished to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced software.
 - 2.1.3. Except for the right to license warranty above, the above warranties do not cover equipment or third-party software delivered with the GE Healthcare software. Third-party software is identified with a separate part number on the quotation (i) delivered to Customer in the third-party manufacturer/supplier's packaging and with its labeling, or (ii) for which GE Healthcare expressly indicates (either in the quotation or in the product documentation) that the software or equipment is provided with the third-party manufacturer/supplier's warranty in lieu of a GE Healthcare warranty. Such products are covered by the third-party manufacturer/supplier's warranties, to the extent available.
- 2.2. <u>No Other Warranties</u>. NO OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUIET ENJOYMENT, SYSTEM INTEGRATION AND DATA ACCURACY, WILL APPLY.
- 2.3. <u>Sole and Exclusive Remedies for Breach of Warranties</u>. The remedies set forth below are Customer's sole and exclusive remedies and GE Healthcare's sole and exclusive liability for warranty claims. These exclusive remedies shall not have failed of their essential purpose (as that term is used in the Uniform Commercial Code) as long as GE Healthcare remains willing to repair or replace defective warranted products or re-perform any non-conforming services for no charge, as applicable, within a commercially reasonable time after being notified of Customer's warranty claim.
 - 2.3.1. If there is any breach of a warranty contained in Section 2.1.1, GE Healthcare will promptly re-perform any non-conforming services for no charge as long as Customer provides reasonably prompt written notice to GE Healthcare.
 - 2.3.2. If there is a breach of warranty contained in Section 2.1.2(i) GE Healthcare will indemnify Customer in accordance with Section 3.3 of the General Terms and Conditions to included as part of this Agreement.
 - 2.3.3. If there is any breach of a warranty contained in Section 2.1.2(ii) (iv) and Customer promptly notifies GE Healthcare of Customer's warranty claim during the warranty period and makes the software available for service, GE Healthcare will, at its option, with respect to the GE Healthcare software, either correct the non-conformity or replace the applicable software. Unless agreed otherwise, warranty service will be performed without charge from 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel. For certain licensed software, GE Healthcare will perform warranty service only at an authorized service center or, in some instances, via a secure, remote connection to a GE Healthcare online center.
- 2.4. <u>Limitations</u>. GE Healthcare shall not have any obligation to Customer hereunder if the warranty claim results from or arises out of: (i) the use of the software in combination with any software, tools, hardware, equipment, supplies, accessories or any other materials or services not furnished by GE Healthcare or recommended in writing by GE Healthcare; (ii) the use of the software in a manner or environment, or for any purpose, for which GE Healthcare did not design or license it, or in violation of GE Healthcare's written recommendations or instructions on use; (iii) any alteration, modification or enhancement of the software by Customer or any third party not authorized or approved in writing by GE Healthcare (iv) inadequate back-up or virus protection or any other cause external to the software or beyond GE Healthcare's reasonable control. In addition, the warranties set forth above do not cover the software to the extent it is used in any country other than the country to which GE Healthcare ships the licensed software (unless GE Healthcare expressly agrees otherwise in writing). GE Healthcare does not quarantee that the software will operate without error or interruption.



Warranty Statement (United States)

GE Healthcare

- 1. Warranted Products. These warranties cover the purchase and use of the following GE Healthcare products:
- Magnetic Resonance
- Computed Tomography
- Mammography
- Positron Emission Tomography (including scanners, cyclotrons & chemistry labs)
- Nuclear
- X-ray

- Surgical Navigation Systems
- Cardiology
- Ultrasound
- Bone Mineral Densitometry
- Physiological Monitoring
- Small Animal Imaging
- C-Arms
- Advantage Workstation and Server
- Anesthesia Delivery
- Respiratory Care
- Gold Seal
- Phototherapy and other infant care accessories
- Microenvironments, including Giraffe®, Care Plus®, Ohio® Infant Warmer Systems and Panda™ Baby Warmers

2. GE Healthcare Warranties.

- 2.1 Scope. This warranty statement incorporates GE Healthcare's General Terms and Conditions and GE Healthcare's Product Terms and Conditions. GE Healthcare warrants that its services will be performed by trained individuals in a professional, workman-like manner. GE Healthcare will promptly re-perform any non-conforming services for no charge as long as Customer provides reasonably prompt written notice to GE Healthcare. The foregoing service remedy, together with any remedy provided herein, are Customer's sole and exclusive remedies (and GE Healthcare's sole and exclusive liability) for warranty claims. These exclusive remedies shall not have failed of their essential purpose (as that term is used in the Uniform Commercial Code) as long as GE Healthcare remains willing to repair or replace defective warranted products or re-perform any non-conforming services for no charge, as applicable, within a commercially reasonable time after being notified of Customer's warranty claim. NO OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, QUIET ENJOYMENT, SYSTEM INTEGRATION AND DATA ACCURACY, WILL APPLY.
- 2.2 <u>Term Usage</u>. "Warranted Product" is a collective term which includes both the above-listed manufactured equipment and licensed software, with the exception of Healthcare IT Products, purchased by and/or licensed to (as applicable) Customer under the relevant GE Healthcare Quotation. Where an item of equipment has software code embedded in it, the code will only be considered licensed software under this warranty statement if the applicable GE Healthcare Quotation provides a separate part number for that software.
- 2.3 <u>Equipment Warranty</u>. Except as indicated otherwise below, GE Healthcare warrants the equipment will be free from defects in title and that for 1 year from the Warranty Commencement Date (as defined below) (i) the equipment will be free from defects in material and workmanship under normal use and service and (ii) except for equipment manufactured in compliance with Customer's designs or specifications, the equipment will perform substantially in accordance with GE Healthcare's written technical specifications for the equipment (as such specifications exist on the date the equipment is shipped) (the "Specifications"). This warranty covers both parts and labor and is available only to end-users that purchase the equipment from GE Healthcare or its authorized distributors. Customers purchasing through an authorized distributor must contact GE Healthcare promptly following such purchase to enable this warranty.
- 2.4 Software Warranty. Except as indicated otherwise below, GE Healthcare warrants for 90 days from the Warranty Commencement Date that (i) the licensed software will perform substantially in accordance with the applicable Documentation (as defined herein), (ii) it has not inserted any Disabling Code (as defined herein) into the licensed software and (iii) it will use reasonable commercial efforts consistent with industry standards to scan for and remove any software viruses before installation of the applicable Warranted Product. Except as indicated otherwise below, GE Healthcare warrants that it has the right to license or sublicense the licensed software to Customer for the purposes and subject to the terms and conditions set forth in GE Healthcare's General Terms and Conditions. As used in this warranty statement, (i) "Disabling Code" means computer code that is designed to delete, interfere with, or disable the normal operation of the Warranted Product; provided, however, that code included in the licensed software that prevents use outside of the license scope purchased for the software will not be deemed to be Disabling Code and (ii) "Documentation" means the GE Healthcare user manuals, online help functions, technical specifications and user instructions regarding the operation, installation and use of the software as made available by GE Healthcare to Customer.
- 2.5 Pre-owned Equipment. GE Healthcare's Gold Seal Preferred Products (certain pre-owned GE Healthcare equipment) and GE Healthcare's certified pre-owned Bone Mineral Densitometry Products are provided with GE Healthcare's standard warranties carrying the same duration as the new equipment warranty, but in no event exceeding 1 year (unless otherwise provided in writing by GE Healthcare). Except as expressly provided in this paragraph or in the applicable GE Healthcare Quotation, used and/or pre-owned equipment is not warranted by GE Healthcare.
- 2.6 <u>Healthcare IT and X-Ray Tubes.</u> GE Healthcare X-ray and Image Intensifier Tubes, Maxiray X-ray Tubes and GE Healthcare IT Products are covered by a separate warranty statement provided in an applicable GE Healthcare Quotation.

- 2.7 Third-Party Software and Equipment. This warranty statement does not cover Third-Party Software and Equipment (as defined herein) delivered with the Warranted Products (commonly identified by NL or NW series numbers in GE Healthcare's Quotation). "Third-Party Software and Equipment" means any non-GE Healthcare software or equipment (i) delivered to Customer in the third-party manufacturer/supplier's packaging and with its labeling or (ii) for which GE Healthcare expressly indicates (either in the GE Healthcare Quotation or in the product documentation) that the software or equipment is provided with the third-party manufacturer/supplier's warranty in lieu of a GE Healthcare warranty. Such products are covered by the third-party manufacturer/supplier's warranties, to the extent available. Anesthesia monitor mounting solutions Third-Party Software and Equipment purchased directly from GE Healthcare will not be treated as Third-Party Software or Equipment.
- 3. Warranty Commencement. Unless expressly provided otherwise in this warranty statement or the applicable GE Healthcare Quotation, the warranty period begins (the "Warranty Commencement Date") on the earlier of: (i) if GE Healthcare installs the Warranted Product, 5 days after GE Healthcare notifies Customer that it has completed assembly and the Warranted Product is operating substantially in accordance with GE Healthcare's Specifications; (ii) if GE Healthcare does not install the Warranted Product, 5 days after delivery of the Warranted Product to Customer; (iii) the date Customer first uses the Warranted Product for patient use; or (iv) if GE Healthcare is contractually required to install the Warranted Product, the 30th day following shipment to the end-user Customer if installation is delayed for reasons beyond GE Healthcare's reasonable control. The warranty period for any Warranted Product or component furnished to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced Warranted Product. The warranty period for Vital Signs, Inc. Products begins on the date such products are shipped to Customer.
- 4. Remedies. If Customer promptly notifies GE Healthcare of Customer's warranty claim during the warranty period and makes the Warranted Product available for service, GE Healthcare will, at its option (i) with respect to equipment, either repair, adjust or replace (with new or exchange replacement parts) the non-conforming Warranted Product or components of the Warranted Product and (ii) with respect to GE Healthcare's licensed software, either correct the non-conformity or replace the applicable licensed software. Warranty service will be performed without charge from 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel. For certain Warranted Products, GE Healthcare will perform warranty service only at an authorized service center or, in some instances, via a secure, remote connection to a GE Healthcare online center. With respect to GE Healthcare's warranty for the services it provides to Customer, Customer's exclusive remedy is set forth in Section 2.1 above.

Warranty claims for the Warranted Products should be directed through GE CARES at 1-800-437-1171. Warranty claims for accessories and supplies items should be directed through 1-800-558-5102.

5. Limitations. GE Healthcare shall not have any obligation to Customer hereunder if the warranty claim results from or arises out of: (i) the use of the Warranted Product in combination with any software, tools, hardware, equipment, supplies, accessories or any other materials or services not furnished by GE Healthcare or recommended in writing by GE Healthcare; (ii) the use of the Warranted Product in a manner or environment, or for any purpose, for which GE Healthcare did not design or license it, or in violation of GE Healthcare's recommendations or instructions on use; or (iii) any alteration, modification or enhancement of the Warranted Product by Customer or any third party not authorized or approved in writing by GE Healthcare. In addition, this warranty does not cover the Warranted Product to the extent it is used in any country other than the country to which GE Healthcare ships the Warranted Product (unless GE Healthcare expressly agrees otherwise in writing). GE Healthcare does not guarantee that licensed software will operate without error or interruption.

In addition, these warranties do not cover: (i) any defect or deficiency (including failure to conform to Specifications and/or Documentation, as applicable) that results, in whole or in part, from any improper storage or handling, failure to maintain the Warranted Products in the manner described in any applicable instructions or specifications, inadequate back-up or virus protection or any cause external to the Warranted Products or beyond GE Healthcare's reasonable control, including, but not limited to, power failure and failure to keep Customer's site clean and free of dust, sand and other particles or debris; (ii) the payment or reimbursement of any facility costs arising from repair or replacement of the Warranted Products or parts; (iii) any adjustment, such as alignment, calibration, or other normal preventative maintenance required of Customer; (iv) expendable supply items; (v) stockpiling of replacement parts; (vi) any failure of the Warranted Products to use or correctly process dates; and (vii) products not listed in GE Healthcare's Accessories and/or Supplies catalogs at the time of sale, and all service manuals are provided AS IS. For network and antenna installations not provided by GE Healthcare or its authorized agent(s), network and antenna system troubleshooting will be billable at GE Healthcare's standard service rates.

For MR systems, these warranties do not cover (i) any defect or deficiency that results, in whole or in part, from failure of any water chiller system supplied by Customer, (ii) service to any water chiller systems supplied by Customer and (iii) for MR systems with LHe/LN or shield cooler configured superconducting magnets (except for MR Systems with LCC magnets), any cryogen supply, cryogenic service or service to the magnet, cryostat, coldhead, shield cooler compressor or superconductive or resistive shim coils unless the need for such supply or service is caused by a defect in material or workmanship covered by these warranties (GE Healthcare's MR Magnet Maintenance and Cryogen Service Agreement is available to provide supplemental coverage during the warranty period). For Proteus XR/a, Definium and Precision 500D x-ray systems, these warranties do not cover collimator bulbs.

6. Exceptions to GE Healthcare Standard Warranties Described Above.

CT Partial System Equipment Upgrades*: Six (6) months
MR Partial System Equipment Upgrades*: Six (6) months

X-ray Partial System Equipment Upgrades*; High Voltage Rectifiers and TV Camera Pick-Up Tubes: Six (6) months

PET Partial System Equipment Upgrades* (Scanners, Cyclotrons and Chemistry Labs): Six (6) months

Nuclear Partial System Equipment Upgrades*: Six (6) months

GE OEC New or Exchange Service/Maintenance Parts: Ninety (90) days HealthNet Lan, Advantage Review — Remote Products: Ninety (90) days

GE Ultrasound Exchange Probes and Transducers, Ultrasound Water Path attachment Kit: Ninety (90) days

GE Ultrasound Service Replacement Parts: Thirty (30) days

LOGIQBook and Other Handheld/Compact Ultrasound Products: Standard warranty includes (i) repair services at GE Healthcare service facilities, (ii) three (3) business day turnaround repair time for systems shipped via overnight delivery (where available), measured from the date of shipment (GE Healthcare is not responsible for delays in overnight shipment), (iii) seventy-two (72) hour loaner systems or probe replacement service via Fed Ex (shipping charges included), (iv) technical support via telephone from 7:00 am to 7:00 pm Central Time, Monday-Friday, excluding GE Healthcare holidays, (iv) field support/service is available for an additional charge and (v) preventative maintenance for an additional charge. For an additional charge, GE Healthcare will also provide the following enhanced warranty features as part of the system warranty: coverage for system damage due to accidental dropping or mishandling, with a maximum of two (2) replacement systems during the term of the warranty.

Ultrasound Partial System Equipment Upgrades*: Ninety (90) days (Customer will not be credited the value of this warranty against pre-existing warranties or service agreements).

Dash, Solar 8000M, 8000i & Tram: Additional two (2) years of parts only coverage, excluding displays (United States only)

DINAMAP ProCare Vital Signs Monitors: Two (2) years
DINAMAP Pro 100-400V2 Series Monitors: Three (3) years
Enterprise Access: One (1) year ports, ninety (90) days labor

MAC 1600: Three (3) years

MAC 1200: Three (3) years (United States only)

Batteries: Ninety (90) days, except (i) for LOGIQBook batteries, which are warranted for twelve (12) months and (ii) for Nickel cadmium or lead acid batteries for X-ray and mammography systems (which will carry a sixty (60)-month warranty prorated as shown below). For Nickel cadmium or lead acid batteries for X-ray and mammography systems, warranty service will be performed without charge from 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays, and outside those hours at GE Healthcare's then prevailing service rates and subject to the availability of personnel only during the first twelve (12) months of the sixty (60)-month warranty period. For X-ray and mammography systems, if nickel cadmium or lead acid batteries need replacement during their applicable warranty period, Customer will pay the price of the replacement battery in effect on its delivery date less a Pro Rata Credit Allowance (as defined herein). The Pro Rata Credit Allowance for batteries that fail less than twelve (12) months after the warranty begins is one hundred percent (100%). The Pro Rata Credit Allowance for batteries that fail more than twelve (12) months after the warranty begins is:

1 - (# of Mos. After Warranty Commencement /60) x 100%

For the purpose of Pro Rata Credit Allowance, a fraction of a month less than fifteen (15) days will be disregarded, and a fraction of a month equal to or greater than fifteen (15) days will be regarded as a full month.

Care Plus® Incubator: Three (3) years parts, one (1) year labor

Ohio® Infant Warmer Systems and Panda™ Warmers: Lifetime parts warranty on heater cal rod

BiliBlanket® Plus High Output Phototherapy System: Two (2) years on Light Box and eighteen (18) months on Fiberoptic Pad

Microenvironment and Phototherapy expendable components, this includes but is not limited to patient probes, probe covers and light bulbs: Thirty (30) days

GE OEC refurbished c-arms: Twelve (12) months after installation

Oximeters: Three (3) years from installation, or thirty-nine (39) months from GE Healthcare invoice, whichever occurs sooner

Tec 7 Vaporizers: Three (3) years
Tec 6 Plus Vaporizers: Two (2) years

X-ray and Image Intensifier Tubes and Maxiray X-ray Tubes: See GE Healthcare Warranty Statement X-Ray an Image Intensifier Tubes

Accessories and Supplies: GE Healthcare's catalog and/or website includes a "Service/Warranty Code" which identifies the installation, warranty, applications and post-warranty service, if any, provided for each accessory and supply product. Following are the warranty periods for accessories and supplies:

tor acceptance and supplicati	
Service/Warranty Code T	100 Years
Service/Warranty Code V	
Service/Warranty Codes X	15 Years
Service/Warranty Codes F	
Service/Warranty Codes D, J, N, O, R or Z	2 Years
Service/Warranty Codes A, B, C, E, G, L, P, Q, S or Y	
Service/Warranty Code H	
Service Marranty Code K and all Vital Signs Inc. products	3 Months
Service/Warranty Code M	1 Month
Service/Warranty Code M	Out of Box Failure Only

^{*} NOTE: For partial system equipment upgrades, the warranty applies only to the upgraded components



GE Healthcare

Warranty Codes For Accessories And Supplies

Service / Warranty Codes. If Customer promptly notifies GE Healthcare of its warranty claim and makes the Product available for service, GE Healthcare will provide the warranty service indicated in the applicable Service/Warranty Code description. The terms and conditions of GE Healthcare's Warranty Statement(s) apply to all warranty claims. Basic Service Premise for Products – GE Healthcare Field Engineers will take the first call for service and either provide direct support or arrange for support from the manufacturer or its dealers as indicated by the individual Service/Warranty Code. If the Service/Warranty Code calls for Product return for repair or in-warranty exchange, Customer must return the Product as GE Healthcare directs. GE Healthcare provides warranty service from 8:00 AM to 5:00 PM local time Monday-Friday EXCLUDING GE HEALTHCARE HOLIDAYS. If a Service/Warranty Code provides for warranty service to be performed on Customer's site, such service is available outside the above hours at GE Healthcare's prevailing service rates and subject to the availability of personnel.

A GE Healthcare directly, or through a sub-contractor, provides the following:

Installation; parts; on-site warranty service to repair, adjust or replace (at GE Healthcare's option and using new or exchange replacement parts) non-conforming products or parts; applications training in some cases (with additional charge); and post-warranty service, at prevailing hourly billed service ("HBS") rates and, in some cases, under GE Healthcare service contracts.

8 GE Healthcare directly provides the following through GE Healthcare's Global Parts Operation (GPO):

New or exchange replacement parts at no charge to correct non-conforming products or parts during the warranty period; new or exchange replacement parts at GE Healthcare's normal prices for post-warranty repairs. **Note:** Installation, applications training and onsite service is the Customer's responsibility. However, GE Healthcare's Field Engineers may be available at prevailing HBS rates. Contact GE CARES for availability.

C GE Healthcare arranges for the third-party Product Manufacturer or its dealers to provide the following:

Installation (in some cases with an additional charge); parts; on-site warranty service to repair, adjust, or replace (at the manufacturer's or dealer's option and using new or exchange replacement parts) non-conforming products or parts; applications training in some cases (some with additional charge); and post-warranty service at prevailing service rates.

D GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and repair or replacement (at the manufacturer's or dealer's option) of defective products or parts. *Note:* The battery for Service/Warranty Code **D** has a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

E GE Healthcare directly, or through a sub-contractor, provides:

Installation (in some cases with an additional charge); basic functional troubleshooting (no technical labor) with supplier phone support; and coordination of <u>unit</u> exchange or loaner program for in-factory service.

GE Healthcare arranges for the third-party Product Manufacturer or its dealers to provide in-factory service:

At no charge during the warranty period and at manufacturers or dealer's prevailing service rates outside of the warranty period. Products must be returned to the manufacturer or dealer, at GE Healthcare's expense during warranty and Customer's expense after warranty, for repair.

F GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and replacement of non-conforming products or parts, which Customer returns to the manufacturer or dealer during the warranty period. *Note:* For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

G, J, O and Q GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Start up and commissioning; basic functional troubleshooting (no technical labor) with supplier phone support 24/7; and warranty service to repair, adjust, or replace (at the manufacturer's or dealer's option) non-conforming products or parts (excluding installation, time and material). Note: The UPS battery for Service/Warranty Code G has a 9-year pro-rated warranty to cover non-conforming material. Start up and commissioning for Service/Warranty Code O applies only to 10 KVA and above. The UPS battery for Service/Warranty Codes O and Q has a 1-year warranty to replace the product. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate. Warranty service for Service/Warranty Codes G and O is provided On-site. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

H. K. L and M GE Healthcare directly provides the following:

Exchange of non-conforming products, which Customer returns to GE Healthcare during the warranty period. *Note:* Installation, parts, applications training, and on-site service is the Customer's responsibility.

N, R and S GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Installation; Preventative Maintenance; and parts and labor. **Note:** Post-warranty service, at manufacturer's prevailing HBS rates, and in some cases, under GE Healthcare service contracts. The battery for Service/Warranty Code R has a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.

P GE Healthcare directly provides the following:

Replacement of non-conforming components. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

T, V and X GE Healthcare directly provides the following:

Replacement of Product only; GE Healthcare will not replace patient records; and product is warranted only for image legibility. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

W GE Healthcare directly provides the following:

Replacement of Product only for Out of Box failure. **Note:** Installation, parts, applications training, and on-site service is the Customer's responsibility.

Y and Z GE Healthcare refers to the Product Manufacturer warranty, which provides the following:

Basic functional troubleshooting (no technical labor) with supplier phone support and replacement of non-conforming components. **Note:**All electrical components (excluding the UPS) for Service/Warranty Code **Z** have a 1-year warranty. For detailed warranty information, please refer to the Product Manufacturer's warranty certificate.



Warranty Statement for X-Ray And Image Intensifier Tubes (United States And Canada)

GE Healthcare

1. Warranty Scope. These warranties cover each GE Healthcare X-ray or image intensifier tube ("Tube") listed in the GE Healthcare Quotation. This warranty statement incorporates GE Healthcare's General Terms and Conditions and GE Healthcare's Product Terms and Conditions.

GE Healthcare warrants that, starting with the Warranty Commencement Date and for the Warranty Period (as defined below): (i) the Tube will be free from defects in title, material and workmanship under normal use and service and (ii) except for Tubes manufactured in compliance with Customer's designs or specifications, the Tube will perform substantially in accordance with GE Healthcare's written technical specifications for the Tube (as such specifications exist on the date the Tube is shipped) ("Tube Specifications"). This warranty statement defines GE Healthcare's warranty obligations for both parts and labor and is available only to end-users that purchase Tubes from GE Healthcare or its authorized distributors. The Warranty Period for all warranties, except the warranty of title and the Patent and Copyright Warranty, is limited in time as shown below.

- 2. Warranty Commencement Date and Warranty Periods. The Warranty Period start date ("Warranty Commencement Date") for Tubes supplied as part of a new system installation will be the system installation date. The Warranty Commencement Date for replacement Tubes is determined by (i) the date GE Healthcare installs the Tube or (ii) if the date of installation is unknown, then the date of GE Healthcare's invoice to Customer or GE Healthcare's authorized distributor, as applicable, and in all cases not later than six (6) months following shipment of the Tube by GE Healthcare. The Warranty Periods are determined as follows:
- <u>Customer Receives A New Tube As Part Of A New System Installation:</u> For Tubes furnished to Customer as part of a new system installation, the Warranty Period for the replacement Tube will be the full term of the warranty, as shown in the chart below.
- <u>Customer Pays A Portion Of The Cost For The New Tube (Pro Rata Calculation Table Applies):</u> For Tubes purchased by Customer with A PRO-RATA ALLOWANCE, the Warranty Period for the new Tube will be the full term of the warranty, as shown in the chart below.
- <u>Customer Pays The Entire Cost For The New Tube</u>: For Tubes purchased by Customer with NO PRO-RATA ALLOWANCE, the Warranty Period for the new Tube will be the full term of the warranty, as shown in the chart below.
- <u>GE Healthcare Pays The Entire Cost For The New Tube:</u> For Tubes furnished to Customer under terms of the FULL WARRANTY PERIOD, as described in the chart, the Warranty Period for the new Tube will be the unexpired term of the warranty applicable to the last Tube for which Customer paid all or a portion of the cost of that Tube. (Note that the Warranty Period is not "reset" for Tubes supplied when GE Healthcare pays the entire cost for the replacement Tube.)
- <u>GE Healthcare Supplied Tubes Under A GE Healthcare Tube Contract</u>: For Tubes furnished to Customer under terms of a GE Healthcare Tube contract, refer to the Tube contract terms for discussion of any warranty provisions for the Tube. (Note that in general, at Tube contract termination, GE Healthcare provides no warranty of any kind on the Tube(s) remaining in the system.)

3. Remedies

3.1. General Remedies Terms. If, within 10 days after Tube failure, Customer notifies GE Healthcare of Customer's warranty claim during the Warranty Period, provides GE Healthcare with the information shown below, and makes the Tube available for service, GE Healthcare will, at its option, either repair, adjust or replace (with new or exchange replacement parts) the non-conforming Tube or parts of the Tube. Customer must provide GE Healthcare in writing (i) GE Healthcare's serial number of the Tube, (ii) the location and GE Healthcare's serial number of the system on which the Tube was installed, (iii) the date the Tube failed, (iv) the date the Tube was removed from service, and (v) the exposure counter reading when the Tube was removed. Warranty service will be performed as detailed below (with some types of service for a charge and other types of service on a no charge basis, as listed below) during GE Healthcare's standard service coverage hours of 8:00 a.m. to 5:00 p.m. (local site time), Monday-Friday, excluding GE Healthcare holidays ("Standard Coverage Hours"), and outside of Standard Coverage Hours at GE Healthcare's then-prevailing service rates (except as otherwise stated herein) and subject to the availability of personnel.

Customer must: (i) use the Tube in accordance with GE Healthcare service instructions and recommendations for the Tube and the system on which it is installed (including warm up and calibration procedures); (ii) perform preventive and corrective maintenance of the Tube utilizing maintenance procedures in accordance with GE Healthcare service instructions and recommendations and using GE Healthcare replacement parts or replacements ports of equivalent quality; and (iii) keep and make available to GE Healthcare, upon request records documenting the above maintenance.

Customer's failure to (i) properly use the Tube, (ii) perform the maintenance described above, (iii) maintain the information required above, (iv) provide the above information or any other information required by this warranty within the designated time periods, or (v) permit GE Healthcare, to verify such information during GE Healthcare's normal working hours will invalidate this warranty.

- 3.2. <u>Determining Tube Charge For Replacement Tubes</u>. Customer will pay the price of the replacement Tube in effect on its delivery date less the applicable Pro Rata Warranty Allowance (if applicable) described in the table that follows. For the purpose of the Pro Rata Warranty Allowance, a fraction of a month less than 15 days will be disregarded, and a fraction of a month equal to or greater than 15 days will be regarded as a full month.
- 3.3. Non-CT Tubes (Radiographic, Radiographic & Fluoroscopic, Vascular, and Mammographic). For Non-CT Tubes, warranty service does not include installation of the replacement Tube in Customer's system, but upon Customer's request, GE Healthcare, will install the Tube at GE Healthcare's then-prevailing service rates. If a replacement Tube is not installed by GE Healthcare, Customer must, not later than 10 days after its installation date, provide GE Healthcare, in writing (i) GE Healthcare's serial number of the replacement Tube, (ii) the location and GE Healthcare's serial number of the system on which the replacement Tube has been installed, (iii) the date of installation, and (iv) the exposure counter reading on the installation date.

3.4. CT Tubes Replaced During Full Warranty Period.

- 3.4.1. <u>Determining Labor Charges For Tubes Replaced During Full Warranty Period</u>. No service charges for the installation of the replacement Tube will be billed to Customer for CT Tubes replaced during the Full Warranty Period when those Tubes are replaced during Standard Coverage Hours.
- 3.4.2. <u>GE Healthcare Pays The Entire Cost For The CT Tube.</u> For CT Tubes furnished to Customer under terms of the FULL WARRANTY PERIOD as described in the chart, there is no charge to Customer for GE Healthcare installation costs for installation during Standard Coverage Hours. For services performed outside the Standard Coverage Hours, the service will be provided at GE Healthcare's prevailing service rates at the time of service, less a credit for the comparable service had it been rendered during the Standard Coverage Hours, so that Customer will pay the net difference. No refund or payment will be issued to Customer or other parties who choose to utilize either in-house or third party service providers for installation of the replacement Tube.

3.5. CT Tubes Replaced During Pro Rata Warranty Period.

- 3.5.1. Determining Labor Charges For CT Tubes Replaced During Pro Rata Warranty Period: Customer will pay GE Healthcare a service charge for the installation of the replacement CT Tube in effect on the date the service is rendered, less the applicable Pro Rata Labor Allowance. (Note that the Pro Rata Labor Allowance may be applied only to charges by GE Healthcare for GE Healthcare supplied labor.) No refund or payment will be issued to Customer or other parties who choose to utilize either in-house or third party service providers for installation of the replacement Tube. GE Healthcare will make a credit allowance at the billing rate for services performed for installation during Standard Coverage Hours. For services performed outside of Standard Coverage Hours, the service will be performed at GE Healthcare's prevailing service rates at the time of service, less a credit for the comparable service had it been rendered during Standard Coverage Hours, so that Customer will pay the net difference.
- 3.5.2. Customer Pays A Portion Of The Cost For The Replacement Tube: For Tubes furnished to Customer with A PRO-RATA WARRANTY ALLOWANCE to correct the warranty failure, the labor allowance multiplier will be calculated at the same pro-rata rate as is applicable to the part that is being replaced or repaired. That allowance will be applied to the prevailing service rates at time of service. Customer will pay the service charge less the Pro-Rata Labor Allowance amount.
- 4. Limitations. GE Healthcare shall not have any obligation to Customer hereunder if the warranty claim results from or arises out of: (i) the use of the Tube in combination with any hardware, equipment, supplies, accessories or any other materials or services not furnished by GE Healthcare or recommended in writing by GE Healthcare; (ii) the use of the Tube in a manner or environment, or for any purpose, for which GE Healthcare did not design or manufacture it, or in violation of GE Healthcare's recommendations or instructions on use; or (iii) any alteration, modification or enhancement of the Tube by Customer or any third party not authorized or approved in writing by GE Healthcare. In addition, this warranty does not cover the Tube to the extent it is used in any country other than the country to which GE Healthcare ships the Tube (unless GE Healthcare expressly agrees otherwise in writing). In addition, these warranties do not cover: (i) any defect or deficiency (including failure to conform to Tube Specifications that results, in whole or in part, from any improper storage or handling, failure to maintain the Tubes in the manner described in any applicable instructions or specifications or any cause external to the Tubes or beyond GE Healthcare's reasonable control, including, but not limited to, power failure and failure to keep Customer's site clean and free of dust, sand and other particles or debris; (ii) any adjustment, such as alignment, calibration, or other normal preventative maintenance required of Customer; (iii) expendable supply items; and (iv) stockpiling of replacement parts.

5. Warranty Periods

TUBE TYPE OR SYSTEM DESCRIPTION (a)	FULL WARRANTY PERIOD (b)	PRO RATA WARRANTY PERIOD (c)	
Radiographic	30 days	24 months	
Radiographic & Fluoroscopic	30 days	24 months	
Vascular	30 days	24 months	
Mammographic	30 days (d)	12 months	
MX150 Voscular	36 months	N/A	
Performix 160A (MX160)	36 months	N/A	
MX120 Fluoroscopic	30 days	18 months	
CT Max	4,000 slices	40,000 slices or 12 months	

TUBE TYPE OR SYSTEM DESCRIPTION (a)	FULL WARRANTY PERIOD (b)	PRO RATA WARRANTY PERIOD (c)	
CT 8800/9000 Metal	4,000 slices	40,000 slices or 12 months	
CT 8800/9000 Graphite	4,000 slices	40,000 slices or 12 months	
GE CGR Graphite	4,000 slices	40,000 slices or 12 months	
GE Technicare CT	4,000 slices	40,000 slices or 12 months	
CT Pace/Sytec 2000-4000	5,000 slices	80,000 slices or 12 months	
CT SRi/Synergy	6,000 slices	80,000 slices or 12 months	
CT 9800 Graphite	5,000 slices	80,000 slices or 12 months	
HiLight Advantage	5,000 slices	80,000 slices or 12 months	
Pegasus on CT/e	5,000 slices	50,000 slices or 12 months	
Pegasus on CT/e Dual	30 days	50,000 slices or 12 months	
ProSpeed/Sytec 6000-8000	9,000 slices	110,000 slices or 12 months	
HiSpeed Advantage on HiSpeed Advantage and CT/I	9,000 slices	140,000 slices or 12 months	
Solarix on LX/I, FX/I, DX/I	10,000 slices	100,000 slices or 12 months	
Solarix 630 on HiSpeed ZX/I	10,000 slices	100,000 slices or 12 months	
Solarix 630 on NX/I Pro	30 days	12 months or 15,000 amp-seconds	
Performix-ADV on CT/I	6 months or 100,000 slices, whichever occurs first	N/A	
Performix-ADV QX/i	6 months or 30,000 amp-seconds, whichever occurs first	N/A	
Performix Ultra on LightSpeed 16, LightSpeed Ultra, LightSpeed Plus, LightSpeed QX/I, HiSpeed QX/I, Discovery LS, Discovery ST	12 months or 70,000 amp-seconds, whichever occurs first	N/A	
Performix Ultra on BrightSpeed 16 (Elite), BrightSpeed 8 (Edge), BrightSpeed 4 (Excel)	12 months or 6,000 patient exams, whichever occurs first	N/A	
Performix Pro80 (D3634T) on LightSpeed Pro 16, LightSpeed RT	12 months or 70,000 amp-seconds, whichever occurs first	N/A	
Performix Pro VCT100 (D3194T) on LightSpeed Pro16	12 months or 70,000 amp-seconds, whichever occurs first	N/A	
Performix Pro VCT100 (D3194T) on LightSpeed VCT, LightSpeed VCT Select, LightSpeed RT16, LightSpeed Xtra, Discovery VCT	12 months or 6,000 patient exams, whichever occurs first	N/A	
Image Intensifier	30 days	24 months	

COMMENTS

(a) For actual catalog numbers, please contact your local GE Healthcare representative.

(b) Initial period of time or amount of use after warranty begins during which a full 100% warranty is provided for a Tube that fails.

(c) Maximum period of time or amount of use during which a Pro Rata Warranty Allowance is provided for a Tube that fails. The Pro Rata Warranty Allowance and the Pro Rata Labor Allowance are calculated as follows:

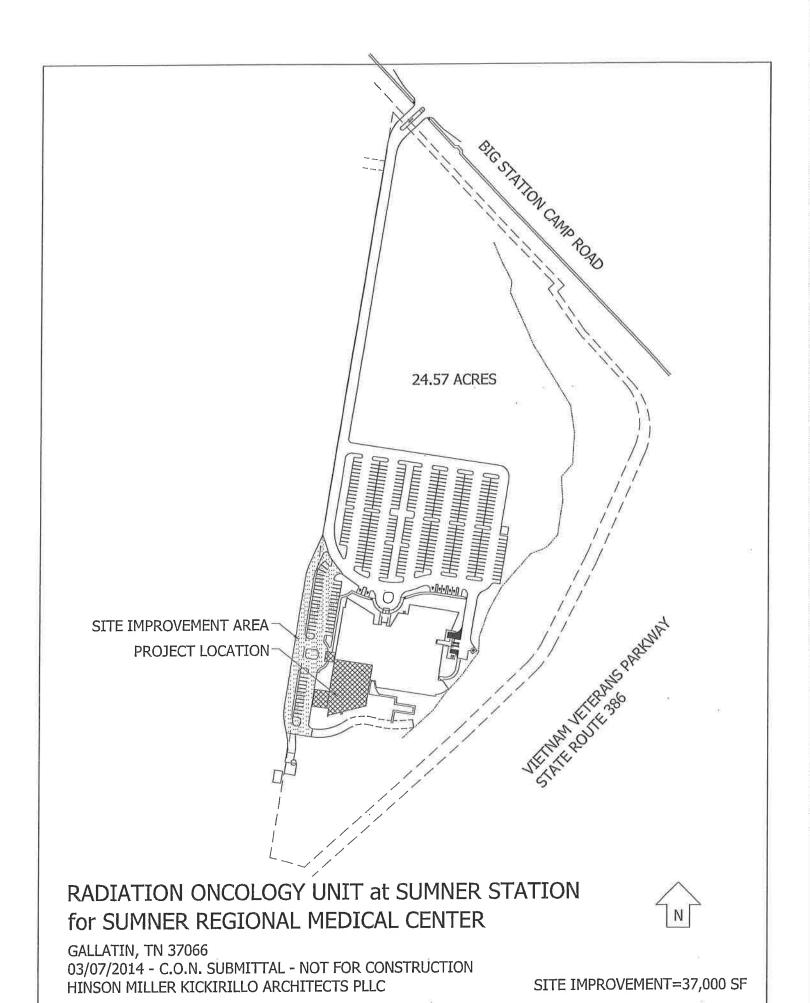
Number of months between date of warranty commencement and date of failure 1 -	X 100
Complete Warranty Time Period	
OR	
Slices Taken or Amp-Seconds	
1	X 100
Complete Pro Rata Warranty Slice or Amp-Second Amount	

The Pro Rata Warranty period ends at the expiration of the maximum time period or the maximum usage amount identified in column (c) above, whichever occurs first.

(d) Mammography tubes included with new systems have a full 12 month, non-prorated warranty. Mammography replacement tubes carry a 30 day full warranty/12 month prorated warranty.

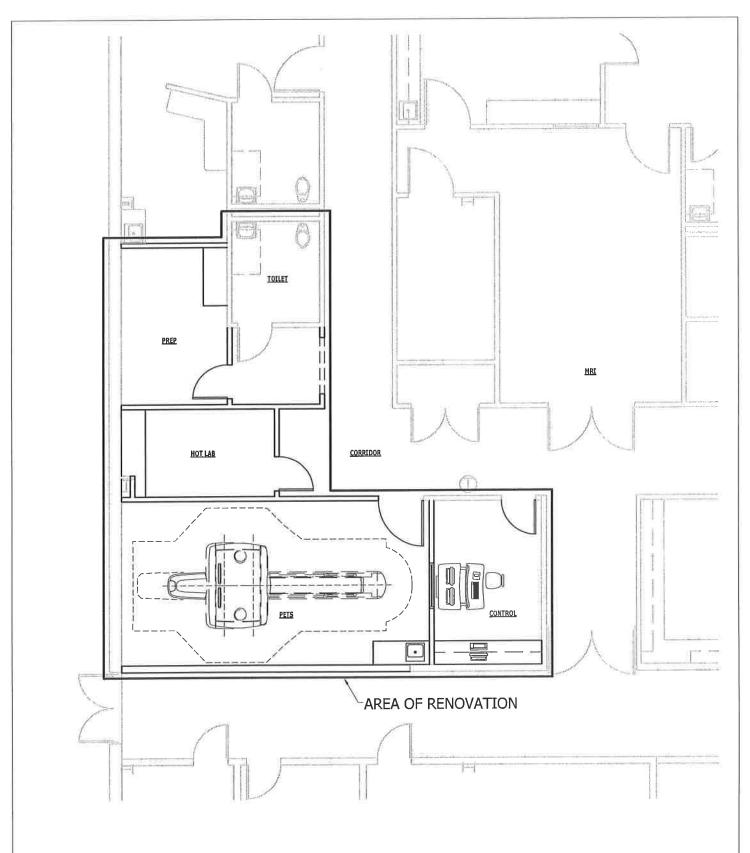
Attachment B, III(A)

Plot Plan



Attachment B, IV

Floor Plan



PET SCANNER at SUMNER STATION for SUMNER REGIONAL MEDICAL CENTER

GALLATIN, TENNESSEE AUGUST 15, 2014 HINSON MILLER KICKIRILLO ARCHITECTS, PLLC C.O.N. SUBMITTAL - NOT FOR CONSTRUCTION



Attachment C, Need – PET Standards, item 6.d.

Protocols

Imaging Orders for Positron Emission Tomography (PET)/Computed Tomography (CT)

Scope: Positron Emission Tomography (PET)/Computed Tomography (CT)

Purpose: To provide guidelines for PET/CT procedures.

Policy: All requests, exam protocols and reports related to PET/CT procedures must be in compliance with current appropriate use criteria for PET/CT studies published periodically by the American College of Radiology. All exam protocols must be approved by the Medical Director of Radiology.

Procedure:

- PET/CT procedure appointments shall be scheduled through the Sumner Regional Medical Center (SRMC) central scheduling department.
- PET/CT procedures will be completed according to a signed order provided by a referring physician. All orders must include reason for examination, diagnosis, physician's signature, date and time.
- All PET/CT reports will be read by board certified radiologists with appropriate Nuclear Medicine and PET/CT training.
- PET/CT reports will be available via hospital information system and images retained in PACS.
- All laboratory testing will be completed and all orders will be verified prior to Fluorodeoxyglucose (FDG) injection.
- The processes, policies and procedures related to PET/CT patient testing shall be monitored for accuracy and compliance.

Attachment C, Need – PET Standards, item 6.e.

Physician CVs

Glenn F. Nabors, Jr. 620 Hartsville Pike Gallatin, TN 37066 (615) 452-9470 Glenn.Nabors@lpnt.net

Certifications

American Board of Radiology

• Effective June 1994

Fellowship

University of South Florida Tampa, FL

• Neuroradiology 1994-1995

Residency

Methodist Hospital Memphis, TN

• Diagnostic Radiology 1990-1994

• Transitional Intern 1989-1990

Education

UT College of Medicine Memphis, TN

Doctor of Medicine June 1989

Tennessee Technological University Cookeville, TN

Electrical Engineering June 1984

Employment

Sumner Radiology PC, Gallatin, TN

December 30, 1996 to Present

East Pasco Radiology Associates, Zephyrhills, FL

July 1995 - December 1996

Licensure

Tennessee 1990

Elton Benjamin Greene

229 Village at Vanderbilt, Nashville, TN 37212 email: ebengreene@gmail.com phone: (901) 233-1392

Certifications

ABR Board Certification in Diagnostic Radiology

Effective July 1, 2012

Fellowship

Vanderbilt Neuroradiology Fellowship

Neuroradiology Fellow, July 2012-Present

Residency

UT/Methodist Healthcare Radiology Residency, Memphis, TN

• Diagnostic Radiology Resident, 2008-present

Transitional Intern, 2007-2008

Education

University of Tennessee Health Sciences Center (UTHSC), Memphis, TN

Doctor of Medicine, 2007

Emory University, Atlanta, GA

• BA in Religion and Psychology, 1998

Honors

Summit Alumni Merit Scholarship, UTHSC

Full tuition, four year medical school scholarship.

Experience

Education Specialist, Philadelphia High School Partnership, 1998-2001

• Facilitated teams of high school students creating service-learning volunteer projects in the Philadelphia, PA metro area.

Publication

Cohen HL, Greene EB, Boulden TP. The Vomiting Neonate or Young Infant. Ultrasound Clinics January 2010; Volume 5, Issue 1: pages 97-

112.

Activities

President, Council for Area and International Outreach, UTHSC

• Oversaw \$16,000 per year in grants for UT medical students traveling abroad and addressing local health disparities in Memphis.

Varsity Swimming, Emory University, 1995-1997

Interests

Photography

Membership

RSNA, member since 2008 ACR, member since 2008

MICHAEL BAZZANI

620 Hartsville Pike Gallatin, TN 37066 (615) 452 9470

EDUCATION | UNIVERSITY OF ILLINOIS SPRINGFIELD IL MEDICAL SCHOOL AUGUST (999 TO MAY 200) UNIVERSITY OF ILLINOIS, SPRINGFIELD IL INTERNSHIP JULY 2003 TO JUNE, 2004 UNIVERSITY OF ILLINOIS, SPRINGFIELD IL RESIDENCY IN RADIOLOGY UNIVERSITY OF MAMI, MAMI, C. FEELOVISHIP MRI

SWPLOYMENT | Sumner Radiology PC, Gallatin, TN July, 2009 to Present

> University Of Miami, Miami, FL July, 2008 to June, 2009 University of Illinois, Chicago, IL July, 2004 to June, 2008

IN RADIOLOGY

BOARD CERTIFIED | American Board of Radiology 6/3/2008

CURRICULUM VITAE WILLIAM LEE KRAFT, MD

PERSONAL INFORMATION

Social Security Number 371 46 9908

Personal Address

2325 Nashville Pike Apt. 902

Gallatin, TN 37066

Birth Date

Dec 24, 1956

Birth Place

Detroit, MI

Citizenship

United States

EDUCATION

High School

Cranbrook School

Bloomfield Hills, MI

Graduated with Honors, 1974

Undergraduate

University of Michigan

Ann Arbor, MI

BA in Zoology with High Honors, 1978

Medical School

University of California at Los Angeles

MD, 1982

Internship

LDS Hospital

Salt Lake City, UT Internal Medicine

June 1982 - June 1983

Residency

Los Angeles County/ University of Southern

California Medical Center

Los Angeles, CA July 1983 to June 1987

Fellowship

Angiography/Interventional Radiology

University of Texas M.D. Anderson Cancer Center

Houston, TX

July 1987 - June 1988

CURRICULUM VITAE WILLIAM LEE KRAFT, MD page 2

LICENSURE

California

Certificate #G51739

Florida

License #ME53465

Tennessee

License #2884533

BOARD CERTIFICATION

Diplomate National Board of Medical

Examiners 1983

Diplomate American Board of Radiology

Diagnostic Radiology 1987

Diplomate American Board of Radiology

Certificate of Added Qualification in

Neuroradiology 1996

HOSPITAL APPOINTMENTS

Medical Staff Membership

Columbia Dade City Hospital Dade City, FL

1988 to 1997

Spring Hill Regional Medical Center

Spring Hill, FL 1995 to 2001

Brooksville Regional Medical Center

Brooksville, FL 1995 to 2001

East Pasco Medical Center

Zephyrbills, FL 1988 to 2002

CURRICULUM VITAE WILLIAM LEE KRAFT, MD page 3

Medical Staff Membership (continued)

Summer Regional Medical Center Gallatin, TN 2002 to present

Trousdale Medical Center Hartsville, TN 2002 to present

Macon County General Hospital Lafayette, TN 2002 to present

Smith County Memorial Hospital Carthage, TN 2002 to present

Carthage General Hospital Carthage, TN 2002 to present

Board of Trustees

Columbia Dade City Hospital Dade City, FL 1993 to 1997

Chief of Staff

Columbia Dade City Hospital Dade City, FL 1996 to 1997

Medical Director

Department of Radiology
East Pasco Medical Center
Zephyrhills, FL
1993 to 1998

Matthew K. Jones

1263 Clark Way Palo Alto, CA 94304 901.258.0389 mkj1560@gmail.com

Professional Education

Stanford University Medical Center

Stanford, CA

Body Imaging Fellowship

2012-2013

Training in all facets of body imaging, including CT, MR, US, image-guided procedures (CT and US), PET/CT, and virtual colonoscopy with additional training in mammography.

American Board of Radiology

Board Certification, Diagnostic Radiology

2012

University of Tennessee/Methodist Healthcare

Memphis, TN

Radiology Residency

2008-2012

Intensive training in all subspecialties of radiology, including mammography (MQSA qualified), nuclear medicine (NRC authorized user), and neuroradiology.

University of Tennessee/Methodist Healthcare

Memphis, TN 2007-2008

Transitional Internship

Memphis, TN

University of Tennessee College of Medicine Doctor of Medicine

2003-2007

Vanderbilt University

Nashville, TN

Bachelor of Science, Neuroscience

1999-2003

Work Experience

Arkansas Methodist Medical Center

Paragould, AR

Adjunct Radiologist

2011-2012

Provided final interpretations of all radiographs, CT, US, and nuclear medicine studies performed during thirteen weekends in a community hospital.

Awards

Vanderbilt University Dean's Select Honors Scholarship (full tuition)

1999-2003

National Merit Scholarship

1999

Current Medical Licenses

California

Professional Memberships

American College of Radiology, Radiologic Society of North America, American Roentgen Ray Society

References

R. Brooke Jeffrey, M.D.
Professor of Radiology, Stanford University
300 Pasteur Dr., Room H1307
Stanford, CA 94305
(650) 723-8463
bjeffrey@stanford.edu

Michael Federle, M.D. Professor of Radiology, Stanford University 300 Pasteur Dr., Grant Building S-092 Stanford, CA 94305 (650) 721-6411 federle@stanford.edu

Randall Scott, M.D.
Professor of Radiology, University of Tennessee Health Science Center 1030 Jefferson Ave.
Memphis, TN 38104
(901) 577-7466
rascott@uthsc.edu

MICHAEL A. HENCEY 1634 LATIMER LANE HENDERSONVILLE, TN 37075 (615) 264-9255

EMPLOYMENT:

Sumner Radiology

Gallatin, TN Jan 2004 to current

Memorial Hospital, Department of Radiology

Tampa, FL 1994-2003

Consultant for James A. Haley VA Hospital

Tampa, FL 1995-2000

EDUCATION:

Fellowship: Neuroradiology

University of South Florida College of Medicine

Tampa, FL 1993-1994

Residency: Diagnostic Radiology Residency University of South Florida College of Medicine

Tampa, FL 1989-1993

Internship: Internal Medicine Internship

University of South Florida College of Medicine

Tampa, FL 1988-1989

Medical Education: University of South Florida College of

Medicine Tampa, FL 1984-1988

Undergraduate Education: University of Florida

Gainesville, FL 1980-1984 Bachelor of Science, Microbiology

MEMBERSHIP IN RADIOLOGY SOCIETIES:

American Society of Neuroradiology, junior member

Radiological Society of North America

Roentgen Ray

Florida West Coast Radiological Society

President 1997-1998 Vice President 1996-1997

CERTIFICATIONS: Passed parts I, II and III of National Medical Boards

Certified in Diagnostic Radiology from American Board

of Radiology June 1993

Certificate of Added Qualification in Neuroradiology from

American Board of Radiology October 1996

LICENSURE

State of Tennessee Medical License 2003 State of Florida Medical License 1989 DEA Registered 1990

RESEARCH AND WORK RELATED EXPERIENCES:

National Institute of Health Summer Research Grant, summer 1985: Combination Chemotherapy Research: Inhibition of Mouse Tumor cell Ribonucleotide Reductase by Various Chemotherapeutic Agents. Department of Biochemistry, University of South Florida

Prosection Dissections: Department of Anatomy, summer 1985
Physician Shadow Program: Clinical Nephrology 1985
Judeo Christian Indigent Care Clinic Volunteer 1985
Research Project: MRI Evidence for Cervical Disk Degeneration
After Anterior Cervical Fusions 1988

PUBLICATIONS AND PRESENTATIONS:

Hencey MA, Murtagh FR, Yost JL, "Magnetic Resonance Imaging of Multiple Sclerosis", Contemporary Diagnostic Radiology, vol. 16, No. 17, 1993

Altus P, Weissman MS, Hencey MA, "A 73 Year Old Woman With Confusion, Rigidity and Fever", Hospital Practice, Pp. 97-98, June 15, 1991

Hencey MA, Murtagh FR, "Measurement of Lumbar Spinal Cord Cross Sectional Area by CT and MRI:, presented at the Southeast Neuroradiologic Society Meeting, Williamsburg, VA October 1991

RESIDENCY HONORS AND AWARDS:

Chief Resident 1992-1993

MEDICAL SCHOOL HONORS AND ACTIVITIES:

Honors Grades in Biochemistry, Physiology, Cross Sectional Anatomy, Medicine Clerkship, Internal Medicine, Acting Internship, Directed Studies in Radiology

Class Rank: Top 20%

Annual Radiology Student Award 1988

Laennec Award for excellence in Clinical Medicine 1988

Intramural Sports: football, basketball, volleyball, and racquetball

Membership in Societies:

American Medical Student Organization American Academy of Family Physicians Florida Academy of Family Physicians USF Family Practice Student Organization Southern Medical Association

COLLEGE HONORS AND ACTIVITIES:

College of Liberal Arts and Sciences Honors Program
Honors Organic Chemistry Program
A.E.D. Preprofessional Honor Society
SAMPSON Volunteer Organization, 1980-1984
-Gainesville VA Hospital Emergency Room
-Gainesville Community Convalescence Center

University of Florida Rugby-Football Club Intramural Sports: football, basketball

LOCUM TENENS: Multiple local outpatient diagnostic centers

PERSONAL: Birthdate: February 10, 1962

Birthplace: Plant City, FL Marital status: Married

Activities: Biking, scuba diving, racquetball, rugby, and weightlifting,

REFERENCES: Available upon request

320 OLD HICKORY BOULEVARD - UNIT #2807 - NASHVILLE, TN 37221

PHONE (915)500-7990 E-MAIL BRENT FRISBIE@VANDERBILT EDU

K. FRISBIE, MD

EDUCATION

1995 - 1999

Birmingham - Southern College (BSC) Birmingham, AL

1999 - 2003

Vanderbilt Medical School

Nashville, TN

PROFESSIONAL EXPERIENCE

July 2003 -- June 2004

1

Internsbip - Medicine

Baptist Hospital - Nashville, TN

July 2004 - Present

Residency - Radiology

Vanderbilt University

PATENTS AND PUBLICATIONS

Surveillance of childhood influenza virus infection: what is the best diagnostic method 1256 for archival samples? J Clin Microbiol. 2004 Mar;42(3):1181-4.

AWARDS RECEIVED

- Amos Christie Scholarship Vanderbilt Medical School
- Summa cam laude with B.S. in Mathematics BSC
- Acton Award Highest canking graduate in Mathematics at BSC
- All American Men's Soccer BSC

Board Examinations Passed:

- Radiologic Physics September 2005
- USMLE Step 3 February 2004
- USMLE Sup 2 November 2002
- USMLE Step 1 June 2001

JASON ROTH

620 Hartsville Pike Gallatin, TN 37066 | (615) 452-9470

EDUCATION | UNIVERSITY OF TENNESSEE, KNOXVILLE TN

Completed December 2001

University of Tennessee, Memphis, TN

Medical School completed May 2006

Memorial Health, University Medical Center, Savannah, GA

Internship July, 2006 to June, 2007

Baptist Memorial Hospital, Memphis, TN

Residency in Radiology July, 2007 to July 2011

EMPLOYMENT | Sumner Radiology PC, Gallatin, TN

August 2011 to Present

Baptist Memorial Hospital, Memphis, TN

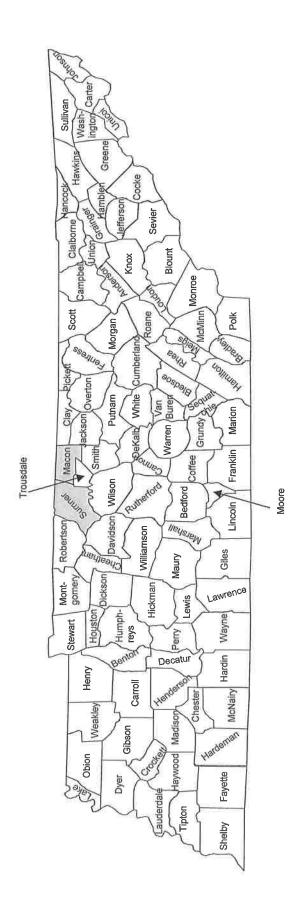
July, 2007 to July, 2011

BOARD CERTIFIED IN RADIOLOGY

American Board of Radiology 5/25/2011

Attachment C, Need - 3

Service Area Map



Attachment C, Need – 4.A.(1)

Demographic Information

U.S. Department of Commerca

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People Business Geography Data Research Newsroom Search

State & County QuickFacts

Sumner County, Tennessee

People QuickFacts	Sumner County	Tennessee
Population, 2013 estimate	168,888	6,495,978
Population, 2012 estimate	165,927	6,454,914
Population, 2010 (April 1) estimates base	160,645	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	5.1%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	3.3%	1.7%
Population, 2010	160,645	6,346,105
Persons under 5 years, percent, 2012	6.2%	6,3%
Persons under 18 years, percent, 2012	24.6%	23.1%
Persons 65 years and over, percent, 2012	13.8%	14.2%
Female persons, percent, 2012	51.2%	51.2%
White alone, percent, 2012 (a)	90.1%	79.3%
Black or African American alone, percent, 2012 (a)	6.7%	17.0%
American Indian and Alaska Native alone, percent, 2012	112 21111	
(a)	0.3%	0.4%
Asian alone, percent, 2012 (a)	1.2%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	0.1%	0.1%
Two or More Races, percent, 2012	1.6%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.1%	4.8%
White alone, not Hispanic or Latino, percent, 2012	86.5%	75.1%
Living In same house 1 year & over, percent, 2008-2012	92.70/	
Foreign born persons, percent, 2008-2012	83.7%	84.4% 4.5%
Language other than English spoken at home, pct age 5+,	3.470	4,570
2008-2012 High school graduate or higher, percent of persons age	5.4%	6.6%
25+, 2008-2012	87.0%	83,9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	23.5%	23,5%
Veterans, 2008-2012	13,277	493,980
Mean travel time to work (minutes), workers age 16+, 2008 -2012	27.4	24.1
Housing units, 2012	66,765	2,834,620
Homeownership rate, 2008-2012	72.7%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	15.2%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$175,500	\$138,700
Households, 2008-2012	60,529	2,468,841
Persons per household, 2008-2012	2.64	2.51
Per capita money income in past 12 months (2012 dollars),		
2008-2012	\$27,823	\$24,294
Median household income, 2008-2012	\$55,560	\$44,140
Persons below poverty level, percent, 2008-2012	9,8%	17.3%
Business QuickFacts	Sumner County	Tennessee
Private nonfarm establishments, 2011	2,833	129,489 ¹
Private nonfarm employment, 2011	36,154	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	0.9%	1,6%1
Nonemployer establishments, 2011	13,447	473,451
	• • • • • • • • • • • • • • • • • • • •	**********
Total number of firms, 2007	15,402	545,348
Black-owned firms, percent, 2007	3.2%	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	S	0.5%
Asian-owned firms, percent, 2007	s	2.0%
Native Hawailan and Other Pacific Islander-owned firms,	moone Fe	
percent, 2007	F	0.1%

Hispanic-owned firms, percent, 2007	1.2%	1.6%
Women-owned firms, percent, 2007	24.2%	25.9%
Manufacturers shipments, 2007 (\$1000)	1,741,400	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	1,634,893	80,116,528
Retail sales, 2007 (\$1000)	1,300,149	77,547,291
Retall sales per capita, 2007	\$8,521	\$12,563
Accommodation and food services sales, 2007 (\$1000)	155,496	10,626,759
Building permits, 2012	592	20,147
	Sumner	
Geography QuickFacts	County	Tennessee
Land area In square miles, 2010	529.45	41,234,90
Persons per square mile, 2010	303.4	153.9
FIPS Code	165	47
Metropolitan or Micropolitan Statistical Area	Nashville-	e : e : e :
	Davidson	
	Murfreesboro	
	Franklin,	

^{1:} Includes data not distributed by county.

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits Last Revised: Thursday, 27-Mar-2014 09:57:50 EDT

⁽a) includes persons reporting only one race.
(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information F: Fewer than 25 firms
FN: Footnote on this item for this area in place of data
NA: Not available:
S: Suppressed; does not meet publication standards
X: Not applicable
Z: Value greater than zero but less than half unit of measure shown

U.S. Department of Commerce

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People Business Geography Data Research Newsroom Search

State & County QuickFacts

Macon County, Tennessee

People QuickFacts	Macon County	Tennessee
Population, 2013 estimate	22,701	6,495,978
Population, 2012 estimate	22,531	6,454,914
Population, 2010 (April 1) estimates base	22,248	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	2.0%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	1.3%	1.7%
Population, 2010	22,248	6,346,105
Persons under 5 years, percent, 2012	7.0%	6.3%
Persons under 18 years, percent, 2012	24.9%	23.1%
Persons 65 years and over, percent, 2012	14.9%	14.2%
Female persons, percent, 2012	50.9%	51.2%
White alone, percent, 2012 (a)	97.5%	79.3%
Black or African American alone, percent, 2012 (a)	0.6%	17.0%
American Indian and Alaska Native alone, percent, 2012	inimizara (h	0.404
(a)	0.7%	0.4%
Asian alone, percent, 2012 (a) Native Hawaiian and Other Pacific Islander alone, percent,	0.3%	1.6%
2012 (a)	Z	0.1%
Two or More Races, percent, 2012	0.9%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.7%	4.8%
White alone, not Hispanic or Latino, percent, 2012	93.5%	75.1%
Living In same house 1 year & over, percent, 2008-2012	84.9%	84.4%
Foreign born persons, percent, 2008-2012	4.0%	4.5%
Language other than English spoken at home, pct age 5+, 2008-2012	4.2%	6.6%
High school graduate or higher, percent of persons age 25+, 2008-2012	75.1%	83.9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	8.5%	23.5%
Veterans, 2008-2012	1,309	493,980
Mean travel time to work (minutes), workers age 16+, 2008 -2012	29.8	24.1
Housing units, 2012	9,932	2,834,620
Homeownership rate, 2008-2012	72.8%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	8,9%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$91,800	\$138,700
Households, 2008-2012	8,422	2,468,841
Persons per household, 2008-2012	2.61	2.51
Per capita money income in past 12 months (2012 dollars),		001.001
2008-2012	\$17,666	\$24,294
produce and the second section of the section of the second section of the section of the second section of the s		
Median household income, 2008-2012	\$35,452	\$44,140
Median household income, 2008-2012 Persons below poverty level, percent, 2008-2012	23.5%	\$44,140 17.3%
Persons below poverty level, percent, 2008-2012	23.5% Macon	17.3%
Annual Control of the	23.5% Macon	
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011	23.5% Macon County	17.3% Tennessee 129,489 ¹
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011	23.5% Macon County	17.3% Tennessee 129,489 ¹ 2,300,542 ¹
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011 Private nonfarm employment, percent change, 2010-2011	23.5% Macon County 328 3,297	17.3% Tennessee 129,489 ¹
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011 Private nonfarm employment, percent change, 2010-2011 Nonemployer establishments, 2011	23.5% Macon County 328 3,297 0.5% 1,655	17.3% Tennessee
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011 Private nonfarm employment, percent change, 2010-2011 Nonemployer establishments, 2011 Total number of firms, 2007	23.5% Macon County 328 3,297 0.5%	17.3% Tennessee 129,489 ¹ 2,300,542 ¹ 1.6% ¹ 473,451 545,348
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011 Private nonfarm employment, percent change, 2010-2011 Nonemployer establishments, 2011 Total number of firms, 2007 Black-owned firms, percent, 2007 American Indian- and Alaska Native-owned firms, percent,	23.5% Macon County 328 3,297 0.5% 1,655	17.3% Tennessee
Persons below poverty level, percent, 2008-2012 Business QuickFacts Private nonfarm establishments, 2011 Private nonfarm employment, 2011 Private nonfarm employment, percent change, 2010-2011 Nonemployer establishments, 2011 Total number of firms, 2007 Black-owned firms, percent, 2007	23.5% Macon County 328 3,297 0.5% 1,655	17.3% Tennessee 129,489 ¹ 2,300,542 ¹ 1.6% ¹ 473,451 545,348 8.4%

Hispanic-owned firms, percent, 2007	S	1.6%
Women-owned firms, percent, 2007	s	25,9%
Manufacturers shipments, 2007 (\$1000)	D	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	30,350	80,116,528
Retail sales, 2007 (\$1000)	167,327	77,547,291
Retail sales per capita, 2007	\$7,713	\$12,563
Accommodation and food services sales, 2007 (\$1000)	11,896	10,626,759
Building permits, 2012	15	20,147
	Macon	WEOGET -
Geography QuickFacts	County	Tennessee
Land area in square miles, 2010	307.14	41,234.90
Persons per square mile, 2010 FIPS Code Metropolitan or Micropolitan Statistical Area	72.4 111 Nashville- Davidson lurfreesboro Franklin, TN Metro	153.9 47
	Агеа	

^{1:} Includes data not distributed by county.

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits Last Revised: Thursday, 27-Mar-2014 09:57:48 EDT

⁽a) Includes persons reporting only one race.
(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information F: Fewer than 25 firms
FN: Footnote on this item for this area in place of data
NA: Not available
S: Suppressed; does not meet publication standards
X: Not applicable
Z: Value greater than zero but less than half unit of measure shown

<u>Attachment C, Economic Feasibility – 1</u>

Architect Letter



HINSON MILLER KICKIRILLO

ARCHITECTS PLLC

August 15, 2014

Ms. Melanie Hill Executive Director State of Tennessee Health Services and Development Agency 500 Deadrick Street, Suite 850 Nashville, TN 37243

RE: Sumner Regional Medical Center-Sumner Station Facility

PET Scanner - Verification of Construction Cost

Dear Ms. Hill:

We have reviewed the construction cost developed for a PET scanner proposed for SRMC's outpatient Imaging Center at the Sumner Station facility. The construction cost of \$460,000.00 is based on 1,425 square feet of interior renovation for the scan room and its support spaces.

It is our professional opinion that the construction cost proposed which equates to \$322.80 per square foot is consistent with historical data based on our experience with similar type projects. It is important to note, that our opinion is based on normal market conditions, price escalation, etc.

The project will be developed under the current codes and standards enforced by the State of Tennessee as follows:

2012 International Building Code/2012 International Mechanical Code/2012 International Plumbing Code

2012 International Gas Code

2005 National Electrical Code

2012 NFPA 1, excluding NFPA 5000

2012 NFPA 101, Life Safety Code

2010 FGI Guidelines for the Design and Construction of Health Care Facilities

2002 North Carolina Accessibility Code with 2004 Amendments/2010 Americans with Disabilities Act (ADA)

Sincerely,

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

13-20 cum

Description of construction/renovation of space:

Sumner Regional Medical Center has proposed to add a PET scanner to their existing outpatient Imaging Center at the Sumner Station facility in Gallatin, TN. The project includes approximately 1,425 square feet of interior renovation that will include the PET scan room, control room, prep/staging spaces, patient toilet and a hot lab.

The construction will include demolition and alterations to existing walls, metal stud framing, architectural woodwork, steel doors/frames, wood doors, drywall, interior finishes, radiation protection, mechanical, plumbing, electrical and fire protection systems.

Describe patient access to the proposed location, including public transportation options, if applicable:

Patient access is provided off of Big Station Camp Boulevard. There is a covered entrance at grade level on the North side of the Sumner Station facility that serves the current outpatient Imaging Center suite. Parking for patients is provided directly adjacent this entrance, including handicapped accessible spaces.

Nashville Metropolitan Transit Authority (MTA) serves Gallatin, but not direct service to the Sumner Station facility. Mid-Cumberland Human Resources Agency RTS Public Transit and taxi services are services that can provide public transportation to this facility.

HMKA Project #11193.15 Page 2 of 2

Attachment C, Economic Feasibility - 2

Funding Letter

LIFE POINT HOSPITALS*

September 9, 2014

Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Sumner Regional Medical Center - Certificate of Need for Positron Emission Tomography (PET-CT)

Dear Ms. Hill:

I am the Chief Financial Officer of LifePoint Hospitals ("LifePoint"), the parent organization of Sumner Regional Medical Center ("SRMC"). This letter confirms that LifePoint has sufficient resources to fund the cost of approximately \$2,687,896 for SMRC's project to PET-CT services at its Sumner Station Campus. LifePoint is committed to make these funds available to SMRC.

Thank you for your attention to this matter.

Very truly yours

330 Seven Springs Way, Brentwood, Tennessee 37027
Phone 615.920,7000

LIFEPOINTHOSPITALS.COM

Attachment C, Economic Feasibility - 9

Financial Statement



INCOME STATEMENT

0.00% 7.76% 0.00% -6.77% 0.00% 33.65% 10,58% 3.16% 0.00% 9.98% -14.41% 3.44% 0.00% 69.86% 14.58% 25.89% 37.22% 63.02% 0.55% 2.73% 169,86% 19.35% 19.00% 25.20% -60.26% 10.68% 8.16% 28.83% -12.78% 29.19% 26.06% 13.83% -50.83% 30.21% 22.64% -0.60% -818.62% -28.35% PCT% 81,555 (238,794) (387,397) 6,701,659 (401,509) 43,085,932 874,133 (1,231,953)3,676,710 45,421,235 891,535 2,491,324 164,767 45,162 (143,469)1,395,605) 317,580 (1,057,842)6,701,659 80,735,538 364,804 395,285 5,692,445 8,600,694 454,216 (32,080)368,710 540,886 2,956,877 5,643,817 49,097,945 31,637,593 (1,090,553) 15,746,848 5,268,951 71,044,291 79,644,985 SDollar LAST YEAR 1,898,193 4,089,960 0 0 32,814,458 155,612,894 2,145,286 419,278,555 666,301 166,410,025 3,945,362 5,419,605 85,836,316 9,640,114 417,133,269 (05,409,945 3,484,728 2,583,819 15,628,267 3,945,362 188,427,352 228,705,917 (4,113,520)1,568,810 8,345,188 14,155,996 18,845,556 313,868,610 261,472 16,661,958 2,597,496 5,323,282 170,483 842,292 2,757,053 9,573,629 107,990,254 37,563,831 8,170,297 LPNT GROUP OPERATIONS HIGHTPOINT MARKET YEAR-TO-DATE EASTERN GROUP -2.86% 9.04% 7.03% 0.95% 3.76% 0.00% -4.83% 0.00% 0.00% 20.91% PCT% 31.37% 4.18% 5.73% 121.04% 8.08% 2.86% 0.00% 0.75% 15.66% -0.81% 9.35% 5.06% 0.00% %00.0 2.21% 20.91% 0.00% 3.50% 16.15% 0.00% 6.24% 12.20% 1.27% -8.90% -9.80% 37.77% -0.49% -3.32% -10.34% -8.74% 10241.20% -19.80% 0 951,689 (26,008) 288,209 (89,014) (1,073,449) 16,667,501 15,594,052 2,453,422 18,047,474 (1,165,783) 16,881,691 (884,564) 4,638,950 (727,856) 2,157,196 0 0 (4,247,411) 432,345 2,169,872 233,407 74,158 44,603 315,673 1,841,523 264,792 (802,934),213,275) 148,955) (438, 271)404,687 841,523 273,159 2,667,576 1,429,340 (1,860,351) 2,307,504 15,452,351 **\$Dollar** 2,797,927 89,521,049 23,060,250 479,821,333 2,220,516 482,041,849 127,984,513 (4,181,061) 37,885,283 192,832 5,317,210 3,565,229 37,564,617 184,366,628 221,931,245 257,890,088 (11,847) 8,805,498 4,407,540 369,460,550 2,591,216 752,453 5,915,888 8,003,474 1,843,738 14,254,752 8,805,498 97,188,453 21,870,425 112,581,299 9,018,393 18,976,525 2,519,940 1,690,936 10,121,287 14,785,997 BUDGET 16750 - SUMNER REGIONAL MEDICAL CENTER 14,570,425 10,647,021 36,491,168 201,034,129 237,525,297 260,343,510 19,424,947 24,538,001 384,912,901 40,055,155 426,239 1,054,733 264,792 14,010,639 603,498 2,359,656 88,793,193 25,217,446 8,408,161 1,754,724 4,407,540 10,647,021 (3,748,716)8,215,459 3,471,629 5,291,202 3,853,438 1,225,122) 2,665,374 497,868,807 23,737,102 1,964,095 209,495,957 9,236,723 17,116,174 5,960,491 ACTUAL December 2013 HMO/PPO DISNTS INC ME/MA MED/SURG Capital and Other Costs CHAMPUS CONTRACTUALS REPAIRS & MAINTENANCE MEDICARE CURRENT YR OTHER OPER EXPENSE MEDICAID CURRENT YR Operating Expenses STATE INCOME TAXES TOTAL TAXES INCOME NET INCOME PR YR CONTRACTUALS OTHER NON OPER EXP OTHER OPER INCOME CONTRACT LABOR EMPLOYEE BENEFITS CONTRACT SERVICES INVESTMENT INCOME CHARITY DISCOUNTS PROFESSIONAL FEES OTHER DEDUCTIONS TOT CAPITAL/OTHER TOTAL DEDUCTIONS MANAGEMENT FEES NON INCOME TAXES MINORITY INTEREST FED INCOME TAXES ROUTINE REVENUE PRE TAX INCOME GROSS REVENUE RENTS & LEASES TOTAL OPER EXP TOTAL NET REV DEPRECIATION AMORTIZATION TOTAL PAT REV GROSS IP REV OP ANCILLARY Deductions INSURANCE SUPPLIES SALARIES BAD DEBT INTEREST UTILITIES EBDITA 23.71% %00.0 8.11% -7.80% 155.09% 28.05% 12.25% 26.26% 0.00% 7.76% 0.00% 0.00% 0.00% 0.00% 155,09% 18.04% 13.58% 6.28% 13.49% 12.10% 8.66% 0.00% -17.27% 8.80% 0.00% 1.61% 4.50% -2.02% -14821.97 584.09% -19.99% 67.24% -19.48% -35,21% 120.92% 19.53% -27.14% 155.87% -29.98% ~0.07% 12,86% 48.57% PCT% 250,405 3,579,514 140,476 159,195 62,435 (144,653) 664,703 57,189 26,465 (275,767) 2,816,881 2,541,114 25,142 (1,935,305)(160)33,930 38,089 (1,414,804)(98,003) 1,664,703 119,951 (163,058) 151,896 149,041 (183) 1,566,700 (7770,86) (26,391)(2,055,480) 100,083 2,976,586 ,351,027 3,804,300 (72,890)3,731,410 1,263,186 **\$Dollar** 29,576,528 9,407,931 500,848 ,299,252 237,764 15,611,025 18,716,642 10,552,007 (284,229) 9,042 290,265 13,057 5,809 762,907 1,073,364 216,480 ,078,022 2,329,909 152,808 340,830 256,545 ,073,364 99,200 ,508,286 ,856,843 482,503 469,535 241,241 5,243,724 600,697 3,312,226 3,105,617 20,117,736 38,834,378 38,984,459 150,081 \$Dollar PCT% LAST YEAR **CURRENT MONTH** -10.96% 39.47% -40.75% 7.19% 3,56% 3.18% 0.00% %00.0 0.00% 12.77% 7.84% -1.77% 2.79% 0.00% 11.45% -45.14% 5.09% -0.87% 0.00% 0.00% 0.00% -58.28% -50.81% 202.09% 37.00% -2.32% 29.83% 146.86% 10.81% -15.12% -23.87% 53.80% -0.35% -17.82% (1,921,195) 182449.67 46.49% (179,602) 84,954 (232,348) 42,330 (542,731) 2,087,369 1,544,638 (386,006) 15,640 2,275,820 2,275,820 15,290 (1,896)(23,335)160,008 (452,094)216,573 (7,290)139,058) (7,076)(2,408,024)2,318,150 64,854 (22,524) (107,852)(2,664,386) 76,663 ,222,094 2,581,796 1,140,654 (89,874)1,158,632 ,050,780 (12, 108) A PARTICULAR OF THE PARTICULAR 16,340,537 19,713,118 21,766,928 41,480,046 185,043 41,665,089 11,160,913 (344,154) 32,015,388 9,649,701 16,149 780,382 215,245 570,198 300,117 63,074 367,295 0 ,116,212 462,247 0 462,247 (1,053)218,216 305,506 071,242 599,976 638,049 491,984 ,578,459 148,941 3290,675 142,488 16,998,216 889,733 ,277,517 3,473,375 3,372,581 BUDGET 337,850 315,407 (1,922,248) 367,295 18,427,906 21,257,756 21,380,922 8,496,527 (184,146) 77,191 42,715,869 8,859 39,739 507,624 1,158,542 18,220,310 437,639 3,859,313 2,107,248 33,156,042 641,324 300,199 216,320 298,430 5,663,218 3,896,609 664,830 126,417 2,738,067 2,738,067 42,638,678 3,461,267 1,458,447 ACTUAL 219,151 2,829,850 9,559,827

Current Month and Year-To-Date



BALANCE SHEET 16750 - SUMNER REGIONAL MEDICAL CENTER

LPNT GROUP OPERATIONS EASTERN GROUP HIGHTPOINT MARKET

		r				, 2			
	ENDING		-996,299 0	36,534,227 0 -17,667,053 18,867,174	-586,317 -38,444 -624,761	18,242,413 3,060,038 1,841,590 343,213 22,490,955	6,872,700 114,390,166 27,861,873 0 71,483 149,196,222 -27,788,003 121,408,219	26,363,719 0 26,363,719 100 26,363,819	170,262,993
YEAR-TO-DATE	CHANGE		-1,499,410 0	5,780,070 0 -3,082,046 2,698,024	32,330 -1,792 30,538	2,728,562 16,266 1,443,959 264,631 2,954,008	2,702,700 15,365,552 -605,976 0 65,372 17,527,648 -6,733,424	0 0 348,147 0 -65,313 282,834	14,031,066
	BEGIN		503,111 0	30,754,157 0 -14,585,007 16,169,150	-618,647 -36,652 -655,299	15,513,851 3,043,772 397,631 78,582 19,536,947	4,170,000 99,024,614 28,467,849 0 6,111 131,668,574 -21,054,579 110,613,995	26,015,572 0 26,015,572 0 65,413 26,080,985	156,231,927
December 2013	Balance Sheet	Current Assets	CASH & CASH EQUIVALENTS MARKETABLE SECURITIES Patient Accounts Receivables	PATIENT RECEIVABLES LESS ALLOW FOR GOVT RECEIVABLE LESS ALLOWS - BAD DEBT NET PATIENT RECEIVABLES Final Settlements	DUE TO/FROM GOVT PROGRAMS ALLOWS DUE GOVT PROGRAMS NET FINAL SETTLEMENTS	NET ACCOUNTS RECEIVABLE INVENTORIES PREPAID EXPENSES OTHER RECEIVABLES TOTAL CURRENT ASSETS Property, Plant, Equipment	LAND BLDGS AND IMPROVEMENT EQUIPMENT OWNED EQUIPMENT CAPITAL LEASES CONSTRUCTION IN PROGRESS GROSS PP&E LESS ACCUMULATED DEPRECIATION NET PP&E Other Assets	INVESTMENTS NOTES RECEIVABLES INTANGIBLE ASSETS - NET INVESTMENT IN SUBSIDARIES OTHER ASSETS TOTAL OTHER ASSETS	GRAND TOTAL ASSETS
	ENDING		-996,299 0	36,534,227 0 -17,667,053 18,867,174	-586,317 -38,444 -624,761	18,242,413 3,060,038 1,841,590 343,213 22,490,955	6,872,700 114,390,166 27,861,873 0 71,483 149,196,222 -27,788,003 121,408,219	26,363,719 0 26,363,719 0 100 26,363,819	170,262,993
CURRENT MONTH	CHANGE		-193,037 0	-557,355 0 683,086 125,731	000	125,731 14,406 1,182,270. -14,955 1,114,415	2,702,700 15,365,552 350,572 0 34,888 18,453,712 -652,739 17,800,973	0 0 -53,712 0 -65,313 -119,025	18,796,363
	BEGIN		-803,262 0	37,091,582 0 -18,350,139 18,741,443	-586,317 -38,444 -624,761	18,116,682 3,045,632 659,320 358,168 21,376,540	4,170,000 99,024,614 27,511,301 0 36,595 130,742,510 -27,135,264 103,607,246	0 0 0 0 0 65,413 26,482,844	151,466,630



BALANCE SHEET 16750 - SUMNER REGIONAL MEDICAL CENTER

LPNT GROUP OPERATIONS EASTERN GROUP HIGHTPOINT MARKET

	CIIBBENT MONTH		December 2013		VEAD TO DATE	
BEGIN	CHANGE	ENDING	Liabilities & Equity	BEGIN	CHANGE	ENDING
			Current Liabilites			
3,058,995	-536,652	2,522,343	ACCOUNTS PAYABLE	1.880.744	641,599	2.522.343
2,493,424	359,005	2,852,429	ACCRUED SALARIES	2.631.521	220,908	2.852.429
1,111,487	609,199	1,720,686	ACCRUED EXPENSES	2,289,129	-568,443	1,720,686
0	0	0	ACCRUED INTEREST	0	0	0
0	0	0	DISTRIBUTIONS PAYABLE	0	0	0
318,800	10,825	329,625	CURR PORT - LONG TERM DEBT	216,420	113,205	329,625
873,872	-315,830	558,042	OTHER CURRENT LIABILITIES	936,353	-378,311	558,042
7,856,578	126,547	7,983,125	INCUME LAKES PAYABLE TOTAL CURRENT LIABILITIES	0 7,954,167	0 28,958	0 7,983,125
			Long tenn Deal			
3,703,996	-31,521	3,672,475	CAPITALIZED LEASES	4,002,101	-329,626	3,672,475
0 0	18,113,315	140,010,503 0	INTERCOMPANY DEBI	134,376,671	5,633,832	140,010,503
125,601,184	18,081,794	143,682,978	TOTAL LONG TERM DEBT Deferred Credits and Other Liabilities	138,378,772	5,304,206	143,682,978
0	Ö	0	PROF LIABILITY RISK RESERVES	C		
0	0	0	DEFERRED INCOME TAXES	0	0	0
2,172,172 2,172,172	-2,150,045 -2,150,045	22,127 22,127	LONG TERM OBLIGATIONS TOTAL OTHER LIAB. AND DEF. Εσυίγν	1,971,250 1,971,250	-1,949,123 -1,949,123	22,127 22,127
00	00	00	COMMON STOCK - PAR VALUE	3,945,365	-3,945,365	0
7,927,742	00	7,927,742	RETAINED EARNINGS - START YEAR	3,982,373	3,945,369	7,927,742
7,908,954 0	2,738,067 0	10,647,021 0	NET INCOME CURRENT YEAR DISTRIBUTIONS	00	10,647,021 0	10,647,021
0	0	0	OTHER EQUITY	0	0	0
15,836,696	2,738,067	18,574,763	TOTAL EQUITY	7,927,738	10,647,025	18,574,763
151,466,630	18,796,363	170,262,993	TOTAL LIABILITIES AND EQUITY	156,231,927	14,031,066	170,262,993

Revised 04/25/01

Attachment C, Contribution to the Orderly Development of Health Care - 1

Managed Care Contracts and Transfer Agreements

Last Updated 1-2014	nsurance Contract Name and Network Plan Types	HighPoint Health System Affiliates
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Sumner Regional Medical Center

Trousdale
Medical
Center

Riverview
Regional
Medical
Center

Sumner Homecare and Hospice

			9						
		Hospital	Sumner Inpatient Rehah	Hospital	Hospital	Carthage	Gallatin	Goodlettsville	Hospice
, at			Unit					5	2)
AmeriChoice - (United Healthcare Community Plan as of 01/01/11)	TennCare MCO	•		♦ No	* No Swing	-	•	*	w,
AmeriGroup - Community Care	TennCare HMO	•		♦ No	* No Swing	**	*		"
Aetna	HMO, POS, PPO	•	•	*	*	-	•	•	•
BeechStreet	PPO Network	•	•	*	×				-
Blue Network P (Blue Preferred)	PPO	•	•	♦ No	* No Swing	=		=_	III _{EE}
Blue Network S (Blue Select)	PPO/POS	•	•	♦ No	* No Swing	*	=	•	-
Blue Network V (CoverTN)	HMO Limited Benefit Policy	No Wound Care	•	♦ No Swing	* No Swing	-	-	**	"
BlueCare / TennCare Select	TN Medicaid Program	•		♦ No	* No Swing	=	•	=_	
Center Care PPO	PPO Network	•	•	*	*		-	-	
Cigna Correl Work Comp	HMO, POS, PPO	•	•	*	*				
First Health (Includes CCN PPO)	PPO Network		•	•	* >				
Great West Healthcare	HMO, POS, PPO	•	•	*	×				
HealthScope Benefits (Access the CenterCare Network in TN)	PPO Network	•	•	*	*			•	
HealthSpring Commercial Plans	HMO, POS	•	•	*	×		-	-	-
HealthSpring Medicare Advantage Plans	Medicare HMO and PPO	•	•	*	*			-	
Himana Medicare PDO	Modicar DDO			•	×				-
MultiPlan	PPO Network	•		•	× 3				
NovaNet	PPO Network	•	•	*	×			•	
PPO USA (GEHA)	PPO Network	•	•	*	×				
ppoNext	PPO Network	•	•	*	*			-	100
Prime Health Services	PPO Network	•	•	•	*	-	-	•	
Private Health Care Systems (PHCS)	PPO Network	•	•	*	*				
Provider Networks of America (ProNet access Signature PPO in TN)	PPO Network			k	¢ >				
Signature Health Alliance	PPO Network	•	•	•	×				18
Synergy Health Network	PPO Network and Work Comp	•	•	*	×			-	
Tricare Military Services (Humana Prime Plan)		•	•	*	*	-			
USA Health Network (USA MCO)	HMO, POS, PPO			•	×		-		-
Windsor	Medicare HMO	•		•	* >				
Windsor - Geopsych		•			×				
Modification Advantage of the printing of the	1								
facilities can treat these patients.	Private Hee Hor Service	•	•	•	×	•	*	•	111



() () () ()	2011年1日	SECTION S	My	My Custom Report		STREET, STREET	10000000000000000000000000000000000000
Contract Number	Contract Type	Contracting Entity	Department	Effective Date	Expiration Date	sible Party,	Vendor Other Party
66588.12267 <u>C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	3/16/1999	03/15/2015	Melton, Anne	Hendersonville Nursing Home, LTD.
66588.12270C 66588.12272C 66588.12274C 66588.12282C	Transfer Agreements Transfer Agreements Transfer Agreements Transfer Agreements	Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC Sumner Regional	Administration Cardiology Administration	3/29/2010 7/30/2009 12/20/1993	03/28/2015 07/31/2016 12/19/2014	Melton, Anne Melton, Anne Melton, Anne	RAI Care Centers of Gallatin I, LLC Centennial Medical Center NHC of NHC
66588.12285C 66588.12288C	Medical Center, LI Transfer Agreements, Summer Regional. Medical Center, LI Transfer Agreements, Sumner Regional Medical Center, LI	Medical Center, LLC Summer Regional Medical Center, LLC Sumner Regional Medical Center, LLC	:Administration Administration	6/1/2007 12/20/1993	05/31/2015 12/19/2014	Melton, Anne Melton, Anne	Mostmoreland Golden Living Hartsville Convalescent Center
66588.12298C 66588.12303C	Transfer Agreements Transfer Agreements	Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC	Administration Administration	1/30/1998 9/1/1999	01/29/2015 08/31/2014	Melton, Anne Melton, Anne	LifeTrust America, Inc Madison Healthcare and Rehabilitation Center
66588.12310C 66588.12313C 66588.12315C 66588.12316C	Transfer Agreements Transfer Agreements Transfer Agreements Transfer Agreements	Sumner Regional: Medical Center, LLC Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC	Administration Administration Administration Administration	9/27/1994 12/20/1993 9/1/2006 11/21/1993	09/26/2014 12/19/2014 08/31/2014 11/20/2014	Melton, Anne Melton, Anne Melton, Anne Melton, Anne	Middle Tennessee Rehab at Sumner Gallatin Health Care Associates Patient Partners. Surgery Center Highland Manor
66588.12328C 66588.12331C 66588.12334C 66588.12370C	Transfer Agreements Transfer Agreements Transfer Agreements Transfer Agreements	Medical Center, LLC Sumner Regional Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC Sumner Regional Medical Center, LLC	Administration Administration Administration Administration	2/1/2000 10/18/1999 5/1/2011 11/7/2011	01/31/2015 06/25/2015 06/25/2015 04/30/2015 11/06/2014	Melton, Anne Melton, Anne Melton, Anne Melton, Anne	Vanderbilt Children's Hospital Summit Medical Center Saint Thomas Hospital Riverview Regional Medical Center South
66588.12378C	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	10/26/1999	10/25/2014	Melton, Anne No. Of Contract:	Green Surgery Center, LLC

SRMC Transfer Agreements 8 21 14

Attachment C, Contribution to the Orderly Development of Health Care – 2

Letter of Support

MEDICAL ONCOLOGY/ HEMATOLOGY

Dianna L. Shipley, M.D. Mathew J. Joseph, M.D.

Amy Cox, APRN-BC, AOCNP Cyndi M. Adair, ACNP-BC

> Ms. Melanie Hill Executive Director Tennessee Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

Re: <u>Summer Regional Medical Center - Certificate of Need</u>
<u>Application to Initiate PET Service</u>

Dear Ms. Hill:

We are submitting this letter regarding the proposal by Sumner Regional Medical Center to initiate PET service at its Sumner Station Campus.

Tennessee Oncology is composed of 75 medical oncologists and hematologists, with over 30 practice locations throughout Middle Tennessee, Chattanooga, and Northwest Georgia. We serve more cancer patients in Middle Tennessee than any other oncology group. One of our locations in Middle Tennessee is our clinic in Gallatin in close proximity to Sumner Regional Medical Center.

PET is a critically important service for cancer diagnosis and treatment planning. We support the decision by Sumner Regional to initiate PET services at its Sumner Station Campus. PET services are not currently available in the community, and patients from this area are required to travel to Nashville to have PET scans. The availability of PET service at Sumner Station will reduce the travel burdens on cancer patients, many of whom are elderly. We urge the Agency to approve the request by Sumner Regional.

Very truly yours, Dunia L. Shipley NO

Attachment C, Contribution to the Orderly Development of Health Care – 7(c)

License and Joint Commission Documentation

Board for Aicensing Bealth Care Facilities

Tennessee State of

No. of Beds_

DEPARTMENT OF HEALTH

This is to certify, that a license is hereby granted by the State. Department of Health to

SUMMER REGIONAL MEDICAL CENTER, LLC	to conduct and maintain a
Hospital SUMNER REGIONAL MEDICAL CENTER	
Goaled at 555 HARTSVILLE PIKE, GALLATIN	
County of SUMNER , Gennessee.	a
This license shall expire. JUNE 25	2015 , and in subject.
to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable,	e assignable or transferable,
and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the	r failure to comply with the
laws of the State of Tennessee or the rules and requiations of the State Department of Health issued thereunder.	of Health issued thereunder.
In Witness Whereof, we have hereunto set our hand and seal of the State this 25TH day of JUNE	day of JUNE , 2014.
In the Distinct Category (igs) of GENERAL HOSPITAL	3



DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

Sumner Regional Medical Center

Gallatin, TN

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Hospital Accreditation Program

September 15, 2012

Accreditation is customarily valid for up to 36 months.

Chair, Board of Commissioners

Organization ID#: 7832 Print/Reprint Date: 01/08/13

Mark R. Chassin, MD, FACP, MPP, MPH

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.









This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

Standard	Standard Text	Total	Addressed 45 Day EPs	Chapter Owner
MM.04.01.01	Medication orders are clear and accurate.	1	0	Tommy Cothron
NPSG.03.04.01	Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. Note: Medication containers include syringes, medicine cups, and basins.	-	0	Becky Grant
UP.01.03.01	A time-out is performed before the procedure.	1	0	0 Becky Grant
ESC 60 Day				
Standard	Standand Text	Total	Addressed 60 Day EPs	Chapter Owner
EC.02.05.09	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	F	0	Mike Messer
15.02.01.20	The hospital maintains the integrity of the means of egress.	1	0	0 Mike Messer
<u>15.02.01.35</u>	The hospital provides and maintains systems for extinguishing fires.	ਜ	0	Mike Messer
MM.03.01.01	The hospital safely stores medications.	1	0	0 Tommy Cothron
MS.08.01.03	Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.	1	0	Stacey Crudup/Tammy Carter
PC.01.02.03	The hospital assesses and reassesses the patient and his or her condition according to defined time frames.	1	0	Anne Melton/Penny Clark
PC.01.03.01	The hospital plans the patient's care.	1	0	O Anne Melton/Penny Clark
PC.03.05.03	For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital uses restraint or seclusion safely.	1	0	Anne Melton/Penny Clark
RC.01.01.01	The hospital maintains complete and accurate medical records for each individual natient.	T	0	Jon Koederitz
RC.02.03.07	Qualified staff receive and record verbal orders.	T	0	0 Jon Koederitz

Sumner Regional Medical Center Organization ID: 7832 555 Hartsville PikeGallatin, TN 37066

Accreditation Activity - Measure of Success Form Due Date: 4/4/2013

HAP Standard MM.04.01.01 Medication orders are clear and accurate.

Elements of Performance:

13. The hospital implements its policies for medication orders.

Scoring C Category:

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual ₉₄ Goal (%):

Month 2 Date: 12/2012

Month 2 Actual 95 Goal (%):

Month 3 Date: 01/2013

Month 3 Actual 98

Goal (%):

Month 4 Date: 02/2013

Month 4 Actual ₉₇ Goal (%):

Actual Average 96
Goal (%):

Optional

Comments:

Standard PC.01.02.03 The hospital assesses and reassesses the patient and his or her condition according to defined time frames. HAP

Elements of Performance:

5. For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a

procedure requiring anesthesia services. (See also MS.03.01.01, EP 8; RC.02.01.03, EP 3)

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 97

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 94

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 94

Actual Average Goal (%): 96

Optional Comments:

HAP Standard PC.03.05.03 deemed status purposes: The hospital uses restraint or seclusion safely.

Elements of Performance:

2. For hospitals that use Joint Commission accreditation for deemed status purposes: The use of restraint and seclusion is in accordance with a written modification to the patient's plan of care.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 84

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 100

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 100

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 100

Actual Average Goal (%): 96

Optional Comments:

HAP Standard UP.01.03.01 A time-out is performed before the procedure.

Elements of Performance:

5. Document the completion of the time-out. Note: The hospital determines the amount and type of

documentation.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 95

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2012

Month 3 Actual Goal (%): 99

Month 4 Date: 2/2012

Month 4 Actual Goal (%): 98

Actual Average Goal (%): 97

Optional Comments:

Attachment C, Contribution to the Orderly Development of Health Care – 7(d)

Survey and POC



OCT 18 2006

STATE OF TENNESSEE DEPARTMENT OF HEALTH BUREAU OF HEALTH LICENSURE AND REGULATION MIDDLE TENNESSEE REGIONAL OFFICE 710 HART LANE, 1ST FLOOR

NASHVILLE, TENNESSEE 37247-0530 PHONE (615) 650-7100 FAX (615) 650-7101

October 17, 2006

R. Bruce James, Administrator Sumner Regional Medical Center 555 Hartsville Pike Gallatin, TN 37066

Dear Mr. James:

Enclosed is the statement of deficiencies developed as a result of the state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

Please provide us with documentation to describe how and when these deficiencies will be corrected. This information should be received in our office within ten (10) calendar days after receipt of this letter. We are requesting that you assure correction of the cited deficiencies no later than sixty (60) days from the date of the survey. A follow-up visit may be conducted, if your allegation of correction is reasonable and convincing. Failure to provide an acceptable plan of correction could result in a referral to the Board of Licensing Health Care Facilities for whatever action they deem appropriate.

In order for your Plan of Correction (PoC) to be acceptable, it should address the following:

- 1. How you will correct the deficiency;
- 2. Who will be responsible for correcting the deficiency;
- 3. The date the deficiency will be corrected; and
- 4. How you will prevent the same deficiency from happening again.

Should you have any questions, or if there is any way this office may be of assistance, please do not hesitate to call.

Sincerely,

Nina Monroe, Regional Administrator Middle Tennessee Regional Office

Enclosure NM/dv

	TOF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLII IDENTIFICATION NU TNP531116		(X2) MULTIF A. BUILDING B. WING	9 7727	(X3) DATE : COMPI	
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	chapter require tha policy, plan, proced concerning a subjethe required policy, provisions. A hosp policy also violates establishing the recommendation of the state of the provision of the provision of the state of the state of the provision of the state of the provision of the state of the s	rules and regulations at a licensee develop dure, technique, or syect, the licensee shall maintain it and adhesital which violates a the rule and regulatiquirement. met as evidenced by ion interview and recomined the facility fails sions of the facility fails sions of the facility and "Metal Devices" and "Metal Devices" and "Metal Devices" and the ton 10/11/06 at 10;4 Patient whom had two mand the other Intraversing the patients right subclavian and the other Intraversing the patients right procure and occumentation of the dress and documentation of the dress and occumentation occurrences.	a written ystem I develop ere to its required ion y: cord ed to policies edication de facilities 0 AM in yo vas area of nous arm essings in the Medical icians inen 10/10/06. ive Care	H 404			

Division	of Health Care Fac	cilities					
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H 404	Continued From page 1			H 404			
	"Intravascular Devices" reads on page 2 of the policy "I. Documentation 1. Record date and time of catheter insertion on label provided in the IV start kit and attach to IV dressing." Tour of the facilities operating room on 10/10/06 at 11:00 AM in room 1 revealed 22 milliliters of a white liquid in a 30 milliliter syringe located on top of an anesthesia cart unattended. Further observation revealed the cart was unlocked. There was no label noted on the syringe containing the 22 milliliters of the white liquid. Interview with an anesthesiologist in the surgery hallway on 10/10/06 at 11:05 reports "We don't label the propofol." Confirmation was made with the Surgery Director on 10/10/06 at 11:06 AM that the medication should be labeled.						
	Administration" rea Procedure: "12. M on and off the steri if there is only one Labeling occurs whis transferred from the another. 14. Labe strength, amount, if	ties policy labeled "M ds under the section de under the section ledications and soluti le field should be labe medication being use nen any medication of e original packaging the should include drug finot used within 24 hen expiration occurs in	labeled ons both eled even ed. 13. r solution o g name, ours, and				
	interview with Patie Patients revealed a intravenous dressir The findings were of the 4th Floor charge record review on 10	10/06 at 3:15 PM durent # 37 of the 37 same right Port-A-Cath cents with no date and seconfirmed in an intervenues at this time. 10/10/06 at 3:20 PM regions of the commente documente	npled ntral line ignature. iew with Medical evealed a				

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Division	of Health Care Fac	ilities					
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		1117531110	CTREET AND	DECC OTY	STATE, ZIP CODE	10/1	1/2000
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H 404	nursing notes at 8:4 facility policy to date dressings was conf by the Director of M Floor charge nurse, entitled, "Intravascu documentation shot and time of the cath provided in the intrathe intravenous dre 1200-8-106 (3)(i)4 (3) Infection Control (i) The central ster supervised by an ereducation and/or exknowledge of bacte principles, who is reimplementing writte the daily operation carea, including: 4. Provisions for mintegrity and design	45 AM on 10/10/06. 'e and initial all intraversimmed on 10/10/06 at ledical/Surgical and the Review of the facility and Include recording the insertion on the avenous start kit and ssing.	enous 3:20 PM he 4th ty policy d that the date label attach to ctions all be on ping and dures for supply ge I shelf life	H 404	DEFIGIENCY		
	Based on observation determined the facilities and package integrated found in the facilities	met as evidenced by: on and interview it wa ity failed to ensure th ity of several random s clinical areas that w anufacturer guideline	e sterility i items vere out				
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	Division	of Health Care Fac	lities					
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	H 647	10:55 AM in the "Lir Intensive Care Unit package in the third contained a package Preoperative Skin Cexpiration date print 2006. Confirmation Care Unit/ Care Copackage was out of Observation during on 10/11/06 at 12:3 items in the third dracabinet. One 18 gauge Insylvated with an expiration of gauge Insylvated with an expiration of gauge Insylvated with an expiration of Gauge Inspector of Women! Accreditation Coord PM.	Intensive Care Unit 10 Intensive Care Unit 10 Inter Cart" located in from the Cart in the cart in the cart in the labeled "Scrub Care Prep Tray" that it it is a made with the laboration at 11:00 AN it is at the cart of the newborrous are Autoguard chest to the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the Autoguard chest in the cart of the emergen in the emergen in the cart of the emergen in the cart of the emergen in the cart of the emergen in th	ront of the realed a hat re had an of June Intensive of that the n nursery ed supply cy supply supply tube 1 2005. The stry 2006.	H 647	DEFICIENCY		
		Sterile Supplies" rev	y policy entitled, "She realed that all expirat sed sterile supplies r d weekly.	ion dated				
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	This Statute is not Based on observatidetermined that the clean and sanitary processing the findings included the clean and sanitary processing the findings included the control of the 4th Floor microwave with driest the unit. The finding patient care coordinated to the coordinate of this unit at 2: patient room with an accompartment. The finding patient care coordinated interview coordinated at this time observation on 10/1 tour of the 2nd Floor microwave with driest the unit. The finding patient care coordinated the unit. The finding patient care coordinated floor at this time.	met as evidenced by on and interview, it was facility failed to provolvysical environment and: 10/06 at 11:10 AM dual (West) kitchen revealed food matter on the gray were confirmed with ator at this time. 10/06 at 2:40 PM durest) kitchen revealed and food matter on the gray were confirmed with ator at this time. Confirmed with a tor at this time. Confirmed with the internal findings were confirmed with the accreditation and available for patient of the observation of the observatio	ring a aled a e inside of ith the inside of ith the entinued empty dried entinued empty dried entinued entinued empty dried entinued entin	H 665			
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Division	n of Health Care Fac	ilities							
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H 665	2nd floor at this time. Observation on 10/tour of the Labor ar revealed a microwathe inside of the uniconfirmed with the paccreditation co. Continued observations in the workroon. The livery, and Reconfirmed with a light yellow liconfirmed with the cat this time and that been removed after.	nator and the director e. 11/06 at 11:50 AM dr nd Delivery unit kitche ave with dried food m it. The findings were patient care coordina coordinator at this time tion at 11:58 AM reve m between the Labor very room (LDR) #1 a white container one- quid. The findings we director of women's s t the container should	uring a en atter on tor and aled a and LDR half full ere ervices I have	H 665	×				
	services that meet to are in accordance we harmacy statutes a staff is responsible to procedures that min function may be deleted organized pharmace. This Statute is not a Based on observation to the statute is not a statute in the statute is not a statute in the statute is not a statute in the statute in the statute is not a statute in the statute	ust have pharmaceuti he needs of the patic vith the Tennessee B and regulations. The for developing policie limize drug errors. T egated to the hospital eutical service. met as evidenced by: on, interview, and pol iled to provide vices in compliance v and procedures.	ents and oard of medical is and his l's		T.				

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H 706	Surgery Department revealed a refrigeration compartment amilliliter clear plastic with an expiration department of the at 10:55 AM revealed front of the nurses of the front of the front of the front of the facility Unusable Drugs (Rounder Rx-036 real Procedure reads, "1 outdated drugs are be returned to the Procedure for the facility policy later the facility later the facility policy later the facility policy later the facility	Preoperative Area in at on 10/10/06 at 10:0 to 10/10/06 at 10:0 to that contained in a 0.9 % saline solution to bag for intravenous ate that reads "June nade with the Directo to 10/10/06 at 10:10 Antensive Care Unit or a dea "Line Cart" local desk that contained a solution with an exploration of the contained at 250 milliliter clear strose solution for interior date of Januals made with the Interior director on 10/11/06 ems. The proper of the proper of the contained of Januals and with the Interior director on 10/11/06 ems. The proper of th	on AM in the side on 500 infusion o6". In of the in a 1 liter piration of the plastic ravenous iny nsive of at 11:00 dated or Policy labeled ile or they will disposal." igs r Rx-037, storage ly for out ling a tour room er for ember	H 706			

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Division of Health Care Facilities STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING TNP531116 10/11/2006 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 (X4) ID PREFIX SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX TAG REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE DEFICIENCY H 706 Continued From page 7 H 706 interview with the medical/surgleal director at this time. Continued observation of the 4th Floor medication Pyxis sytem at 2:55 PM revealed a locked medication refrigerator attached to the Pyxis that contained an opened, one-half full bottle of Citrate of Magnesia labeled Room 433B. An interview with the medical/surgical director at 3:05 PM on 10/10/06 revealed that the Patient had been discharged on 8/31/06. Observation on 10/11/06 at 11:40 AM during a tour of the postpartum unit clean supply room revealed the following expired drugs: One liter bag of Dextrose 5% in Water with an expiration date of September 2006. One liter bag of Dextrose 5% in 0.2% Sodium Chloride solution with an expiration date of September 2006. The above findings were confirmed in an interview with the director of women's services at this time. H 714 1200-8-1-.06 (7)(a) Basic Hospital Functions H 714 (7) Radiologic Services. (a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This Statute is not met as evidenced by: Based on observations, interviews, and policy review the facility failed to ensure the safety of

Division of Health Care Facilities (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING B. WING TNP531116 10/11/2006 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) H 714 H714 Continued From page 8 one radiology employee. The findings included: Observations of the Radiology Department on October 11, 2006, revealed a Registered Nurse (RN#1) working in the Computed Tomography Room at 10:00 am, and in the Nuclear Medicine Room at 10:10 am, without a dose/film badge on his/her person. Interview with RN#1, at 10:00 am, on October 11, 2006, revealed the RN worked as a contract employee in Interventional Radiology, and had been employed at the facility for seven weeks. Interview with the Radiology Department Manager at 10:00 am, on October 11, 2006, confirmed RN#1 should have been wearing a dose/film badge. Review of the facility's Radiation Safety Operations Manual revealed all employees requiring dosimetry shall be issued a standard film badge and/or thermoluminescent dosimeter, and the exposure measurements will be recorded and kept on file. H 730 1200-8-1-.06 (9)(b) Basic Hospital Functions H 730 (9) Food and Dietetic Services. (b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be: 1. A dietitian; or, 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association: or.

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Division	n of Health Care Fac	ilities			4		74.
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H 737	provided ninety (90) instruction in food sexperience as a food health care institution qualified dietitian. This Statute is not Based on review of interview, it was dethave a qualified food The findings included Review of the record Director revealed at Employee the aftern the Employee was real a 90 + hour food second and Diete (g) A minimum of the twenty-four (24) hous supplemental night than fourteen (14) hand breakfast. Add provided to patients This Statute Is not a Based on staff internation.	state-approved cours) or more hours of classic Hospital Funcional and service supervision and service supervision with consultation of the service director. The service director of the service director of 10/10/06, continuous of 10/10/06, continuou	assroom and has and has arin a	Н 737		24	
	supplemental meal. The findings include						

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Division of Health Care Facilities (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WNG TNP531116 10/11/2006 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) H 737 H 737 Continued From page 10 Interview with the facility Food Service Director and shift manager, the morning of 10/10/06, confirmed the Supper was served at 4:15 PM and the Breakfast at 7 AM without a supplemental meal between those hours to the patients. H 739 1200-8-1-.06 (9)(i) Basic Hospital Functions H 739 (9) Food and Dietetic Services. (i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual". This Statute is not met as evidenced by: Based on observation and staff interview, it was determined the dietary department was not maintained in a sanitary manner and cold food exceeded 41 degrees at the trayline. the findings included: Observation during the department tour, at 9:15 AM of 10/10/06, with the Food Service Director present, revealed the following ceiling vents and surrounding ceiling tiles had an accumulation of debris: between the grill and steamer; over the production table and steam jacketed kettle; in the dishroom on the dirty side, clean side and over the 3 compartment sink; by the reach-in refrigerators between the production and catering

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	NT OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIE IDENTIFICATION NUI		(X2) MULT A. BUILDIN B. WING		COMPL	(X3) DATE SURVEY COMPLETED	
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H 739	sections and outsid at 9:38 AM revealed processed and the being used in the diduring the tour revestacked and a case floor of the paper staked and a case floor of the paper staked and temperatures at 11: observation reveale 43 degrees and ser diets. Interview, at manager revealed to temperatures was in	e the diet office. Obe of the dishes were be 3 compartment sink wishroom. Further obstaled four cases of cut of cup lids were store or or eroom. Observation ayline revealed a starecording the food 30 AM. Continued the milk temperatured to the pureed text 11:40 AM, with the she person taking the nestructed to remove a ot in the appropriate	ing was servation ups were ed on the on during ff re was ctured hift	H 739				

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Division of Health Care Facilities (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: 02 - STATE BUILDING A. BUILDING B. WING 10/10/2006 TNP531116 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL (X5) COMPLETE DATE PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PREFIX PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) H 872 H 872 1200-8-1-.08 (2) Building Standards (2) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to maintain the hospital environment for the safety of both residents and staff as required by the Standard Regulation 1200-8-1-08(2) the NFPA 101, 8.5.5.2; 101, 8.5.5.3. The findings included: On 10-10-2006 at approximately 2:00 PM during inspection within the basement equipment room, observation revealed, there were penetrations in both the ceiling and the wall. H 874 H 874 1200-8-1-.08 (4) Building Standards. (4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities, and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are Division of Health Care Facilities (X6) DATE TITLE ABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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FORM APPROVED Division of Health Care Facilities (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION COMPLETED AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** 02 - STATE BUILDING A, BUILDING B. WING_ 10/10/2006 TNP531116 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETE (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEEDED BY FULL **PREFIX** PRÉFIX DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) H 874 H 874 Continued From page 1 conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the Regulatory Codes as required by the Standard Regulation 1200-8-1-08(4) and the Standard Building Code- SBC 1403.2.3. The findings included: On 10-10-2006 at approximately 1:45 PM during inspection within the basement area, observation revealed, a steel lintel carrying brick veneer over a doorway was missing, SBC 1403.2.3. H 893 H 893 1200-8-1-.08 (23) Building Standards. (23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection, testing and observation, it

Division of Health Care Facilities

19, 5, 2, 1,

was determined, the facility failed to maintain the negative air pressure within soiled areas as required by the Standard Regulation

1200-8-1-08(23) and the NFPA 90A; 90B-4; 101,

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

TNP531116

NAME OF PROVIDER OR SUPPLIER

SUMNER REGIONAL MEDICAL CENTER

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED

A. BUILDING 02 - STATE BUILDING (X3) DATE SURVEY COMPLETED

TNP531116

STREET ADDRESS, CITY, STATE, ZIP CODE

555 HARTSVILLE PIKE GALLATIN, TN 37066

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Н 893	Continued From page 2	H 893		
	The findings included:	ĺ		
	On 10-10-2006 at approximately 2:30 PM during inspection within the men's bathroom in the Cath Lab area, testing revealed, the exhaust fan units were not working.			
	Inspection and observation within the Medical Imaging area revealed, the return-air grilles were dusty.			
	Inspection and observation within the elevator equipment room revealed, the exhaust fan unit was dusty.			
erne H	During inspection and observation within the dietary area, observation revealed, both air-return units and exhaust fan grilles were dusty.			
H 951	1200-8-109 (1) Life Safety	H 951		
	(1) Any hospital which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.			
i i	This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the applicable building and fire safety regulations as required by the Standard Regulation 1200-8-1-08(1), and the NFPA 10, 1.5.6; 55, 6.6; 70, 240-5; 70, 373-4; 410-56(d).			

373-4; 410-56(d).
Division of Health Care Facilities

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION

A. BUILDING 02 - STATE BUILDING (X3) DATE SURVEY COMPLETED

TNP531116

B. WING_

10/10/2006

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

555 HARTSVILLE PIKE

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H 951	Continued From page 3		H 951		
	The findings included: On 10-10-2006 at approximately 12:30 Prinspection within the basement shop are observation revealed, the portable fire extinguisher was blocked with equipment was in violation of the NFPA 10, 1.5.6. Inspection within the storage area of the basement mechanical room revealed thre pressurized cylinders which were not sec Violation of the NFPA 55, 6.6. During inspection within the pain clinic of Lab area, observation revealed the use of extension cord. NFPA 70, 240-5. During inspection on the 3rd floor next to rehab area, observation within the electric room revealed, panels TA and TB both has unusual open space under the breakers. Of the NFPA 70, 373-4. During inspection within the basement mechanical equipment area, observation revealed a junction box without any cover During inspection within the ceiling space the east fire doors to the Cath Lab area, observation revealed, there was an open box without any cover plate. Inspection above the west fire doors of the Lab revealed open junction box with loose Those were in violation of the NFPA 70, 410-56(d).	the Cath f an Violation plate. above junction e Cath			



Administrative Offices

October 24, 2006

Ms. Nina Monroe, Regional Administrator State of Tennessee Department of Health Bureau of Health Licensure and Regulation Middle Tennessee Regional Office 710 Hart Lane, 1st Floor Nashville, Tennessee 37247-0530

Dear Ms. Monroe:

The following information is provided in response to the recent state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

ID Prefix Tag: H 404 1200-8-.04 (4) Administration

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

How SRMC will correct the deficiency: We will correct failure to label medication and solutions both on and off the sterile field by following our stated policy and further educating our staff and anesthesiologists.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

Post Office Box 1558 555 Hartsville Pike Gallatin, Tennessee 37066-1588 (615) 451-5519 FAX (615) 451-5523

TATAL

How SRMC will correct the deficiency: We will ensure that all anesthesia carts are locked when not in use.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing of Port-A-Cath" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

ID Prefix Tag: H 647 1200-8-1-.06 (3)(i) 4 Basic Hospital Function

How SRMC will correct the deficiency: We will re-educate stocking personnel on the importance of accuracy of daily checks and ensuring that no items remain in stock after expiration date.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking at expiration dates to ensure compliance and immediate re-education as required.

ID Prefix Tag: H 665 1200-8-1-.06 (3)(o) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately correct and reeducate environmental services associates on proper cleaning of microwave ovens and bed side tables, and disposal of used cleaning materials.

Who at SRMC will be responsible for correcting the deficiency: Director, Environmental Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring these deficiencies remain in compliance.

ID Prefix Tag: H 706 1200-8-1-.06 (6)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately check all supply carts to ensure no expired solutions remain.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring that expired items do not exist.

How SRMC will correct the deficiency: We will ensure that all medications belonging to a specific patient are removed when that patient leaves the hospital. Who at SRMC will be responsible for correcting the deficiency: Director, Pharmacy

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Pyxis units are checked daily by Pharmacy staff. They will ensure this occurs. Spot checks will be conducted on all Pyxis units specifically ensuring that expired items or medications from previous patients do not exist.

ID Prefix Tag: H 714 1200-8-1-.06 (7)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will make sure that all Radiology Department associates wear a dose/film badge.

Who at SRMC will be responsible for correcting the deficiency: Director, Diagnostic Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all diagnostic imagining areas specifically ensuring dose/film badges are worn by all associates working in that area.

ID Prefix Tag: H 730 1200-8-1-.06 (9)(b) Basic Hospital Functions

How SRMC will correct the deficiency: We will enroll the Director, Nutritional Service in a 90 hour food service supervisor course and make sure that he completes the course within two years.

Who at SRMC will be responsible for correcting the deficiency: Vice President, Support Services

The date the deficiency will be corrected: No later than October 11, 2008.

How will SRMC prevent the same deficiency from happening again: Vice President, Support Services will ensure that this requirement is added to the current contract as well as any future contracts and then annually reviewed for compliance.



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

October 1, 2014

Michael Herman, Chief Operating Officer Sumner Regional Medical Center 555 Hartsville Pike Gallatin, TN 37066

RE: Certificate of Need Application -- Sumner Regional Medical Center (Sumner Station

Campus) - CN1409-041

Dear Mr. Herman:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need for the initiation of a positron emission tomography (PET) service in an existing building on the hospital's existing outpatient campus at 225 Big Station Camp Boulevard, Gallatin (Sumner County), TN. Project cost is \$2,887,845.00.

Please be advised that your application is now considered to be complete by this office. Your application is being forwarded to the Tennessee Department of Health and/or its representative for review.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on October 1, 2014. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on December 17, 2014.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,
Melanie M. Hell/W=

Melanie M. Hill Executive Director

MMH:mab

cc: Trent Sansing, CON Director, Division of Health Statistics

Dan H. Elrod, Esq.



State of Tennessee Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 **www.tn.gov/hsda** Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO:

Trent Sansing, CON Director

Office of Policy, Planning and Assessment

Division of Health Statistics

Andrew Johnson Tower, 2nd Floor 710 James Robertson Parkway Nashville, Tennessee 37243

FROM:

Melanie M. Hill MMH/W=

Executive Director

DATE:

October 1, 2014

RE:

Certificate of Need Application

Sumner Regional Medical Center (Sumner Station Campus) -

CN1409-041

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on October 1, 2014 and end on December 1, 2014.

Should there be any questions regarding this application or the review cycle, please contact this office.

MMH:mab

Enclosure

cc:

Michael Herman, Chief Operating Officer

Dan H. Elrod, Esq.



State of Tennessee Health Services and Development Agency Andrew Jackson Building, 9th Floor

Andrew Jackson Building, 9th Flo 502 Deaderick Street Nashville, TN 37243 www.tn.gov/hsda Phor

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to	be published in	The Tennessean (Name of Newspaper)	which is a newspaper
of general circulation in	Sumner	, Tennessee, on or before	September 10 , 20 14 ,
for one day.	(County)		(Month / day) (Year)
======================================		=======================================	
This is to provide official notice accordance with T.C.A. § 68-7 that:	e to the Health Service to the Health Service 11-1601 et seq., and the	ces and Development Agency he Rules of the Health Servic	es and Development Agency,
Sumner Re	<u>egional Medical Cente</u>	r	a hospital (Facility Type-Existing)
(Name of Applicant)			
owned by: Sumner Regional	Medical Center, LLC	_ with an ownership type of _	limited liability Company
intends to file an application f at its existing outpatient cam Gallatin, Tennessee. The projethe purchase of G.E. Discove The project does not involve certificate of need, except pos	npus known as Sumr ect will require build-o ery PET/CT Imaging S a change in licensed	ner Station, located at 225 fout of approximately 1,425 squ System. The total project cost d bed capacity or the initiation	Big Station Camp Boulevard, lare feet of existing space and is approximately \$2,687,896.
The anticipated date of filing the	ne application is:	<u>September 15</u> , 20 <u>1</u>	4
The contact person for this pro	oject is	Dan Elrod (Contact Name)	Attorney (Title)
who may be reached at:	Butler Snow LLI (Company Name)		enue South, Suite 1600 (Address)
Nashville	TN	37201	615 / 651-6702
(City) (Signature)	(State)	-1 /-	(Area Code / Phone Number) an.elrod@butlersnow.com (E-mail Address)
The Letter of Intent must be fill last day for filing is a Saturda this form at the following address	y, Sunday or State Ho ess: Health Services a Andrew Jacks 502 De	eived between the first and the liday, filing must occur on the and Development Agency son Building, 9 th Floor eaderick Street Tennessee 37243	e tenth day of the month. If the preceding business day. File
Development Agency no later the	e a Certificate of Need a nan fifteen (15) days be application is originally	application must file a written no efore the regularly scheduled He scheduled: and (B) Anv other	68-11-1607(c)(1). (A) Any health tice with the Health Services and ealth Services and Development person wishing to oppose the at or prior to the consideration of

HF51 (Revised 01/09/2013 – all forms prior to this date are obsolete)

the application by the Agency.



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor

www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

September 19, 2014

Michael Herman Sumner Regional Medical Center Chief Operating Officer 555 Hartsville Pike Gallatin, TN 37066

RE: Certificate of Need Application CN1409-041

Sumner Regional Medical Center - Initiation of PET service on Outpatient Campus of Hospital

Dear Mr. Herman,

This will acknowledge our September 15, 2014 receipt of your application for a Certificate of Need for the initiation of a Positron Emission Tomography service (PET) on the hospital's existing outpatient campus at 225 Big Station Camp Boulevard, Gallatin (Sumner County).

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

<u>Please submit responses in triplicate by 4PM, September 25, 2014.</u> If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section A, Applicant Profile, Item 3

There appears to be an error with the phone number listed for the owner.

The registration of the owner with the Tennessee Secretary of State's Office is noted. Please also provide a copy of the Corporate Charter or Partnership Agreement.

Describe the existing ownership structure of Sumner Regional Medical Center, LLC and identify the members of the LLC with 5% or more ownership interest.

2. Section B, Project Description, Item I

The executive summary is noted. Based on the hospital's accreditation by the American College of Surgeons, what recommendations from the review were made with respect to adding PET as a diagnostic & treatment planning modality to meet clinical standards of care?

Review of HSDA records revealed that the applicant had a previously approved CON for a mobile PET service on the main hospital campus 1 day per month focusing on use for diagnosing neurodegenerative disease, cerebrovascular accidents, brain tumors and seizure disorders (CN0406-058A). The mobile PET service was not unimplemented and surrendered to HSDA in December 2007. If SRMC could not implement the mobile PET service approved in CN0406-058A, what has changed that it needs a fixed stationary PET unit for cancer diagnosis per this proposed project? Please discuss.

3. Section B, Project Description, Item II.A.

There appears to be an error in the Square Footage Chart. The construction cost in SF Chart amounts to \$455,990 but should be revised to \$460,000 in order to be consistent with the \$322.80 per SF cost and the \$460,000 entered in line item 5 of the Project Cost Chart. Please clarify.

4. Section B, Project Description, Item II.C

The need for the proposed PET service based on the absence of a PET service in Sumner & Macon Counties is addressed here, in the executive summary and the project specific criteria on page 13. In addition to the recap of the TDH report on cancer in Tennessee, the applicant may wish to consult with a program representative of TDH's Tennessee Cancer Coalition to further support the need for the proposed service. If possible, please document the suggestions or recommendations discussed with the TDH representative.

The letter of support from Dr. Shipley, TN Oncology is noted, however, some estimate of referrals would be appreciated. Please provide letters from oncologists stating the estimated monthly PET referrals to SRMC.

In addition to identifying services of the oncology program such as radiation therapy, surgery and chemotherapy services; please provide additional information about SMRC's oncology program that provides a brief description of hospital/medical staff organizational structures for coordinating the activities of the oncology program, including information systems such as its tumor registry and tumor board; and a description of how the proposed PET service can contribute to SRMC's participation in any clinical investigative protocols through formal oncology network relationships with other providers.

5. Section B, Project Description, Item II.E.

Please note that the equipment quote for the base fixed unit cost of \$1,093,866 expired in August 2014. Please provide an addendum or updated quote from the equipment vendor such that the offer will be in effect on the date that the application will be heard by HSDA (December 2014 at earliest).

Please identify the costs associated with the FDG/radioactive material, and identify the terms of the contractual arrangement that might apply with supplier(s), as necessary (a copy of a draft agreement or letter of interest between the applicant and the vendor would be helpful). Please also identify the address and distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

6. Section C. Need Item 1. (Project Specific Criteria - PET Service)

Item 2- it appears that the first sentence would apply to the project (accessible to 75% of the population of Sumner and Macon Counties). Please describe how the proposed PET/CT unit at Sumner Station meets this criterion.

Item 3- it is noted the applicant considered the possibility of a mobile PET unit. Given the proposed utilization that is more characteristic of the criterion for mobile units plus the applicant's previous unimplemented CN0406-058AW, what factors would have to be met to make a mobile service more attractive?

Item 6.c. - It is noted the service will be operated as a part of SRMC on its outpatient campus and is subject to the same emergency plan & procedures. Since this is a new service, how will the applicant handle emergencies specific to the PET/CT? What are the responsibilities of the medical director or on-site physicians for same?

Item 6.g.-the name of the entity that has issued permits for CT services was omitted from the response. While it is understood that a permit would be premature – please list the key requirements that must be met. In your response, it may be helpful to include as an addendum with the 8/15/14 letter from the architect for the project.

7. Section C, Need, Item 5

Please identify the use of PET providers in Davidson County and other areas of TN by residents of Sumner and Macon County for the most recent 3 years. A suggested template is the table below showing utilization by Sumner residents. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

PET Utilization by Sumner County Residents, 2011-2013

Providers with PET Service	Provider Location	Distance from SRMC Sumner Station	2011	2012	2013	% Change '11-'13
Premier	Davidson					
Imaging Alliance	Davidson					
TN Oncology	Davidson					
Centennial	Davidson					
VUMC	Davidson					
All other TN providers	Statewide					
Total -TN						

[•] Note: new provider Source: HSDA Equipment Registry, 2013 Service Utilization Records

Please summarize the strategies being implemented by SRMC other than the proposed relocation of the service that might help SRMC reach the 1,000 minimum utilization standards at some point within 5 years following project completion in October, 2016.

Please identify the projected payor mix for the service in Year 1 as to # procedures and estimated gross revenue by payor in Year 1.

The methodology discussed on page 18 that identifies the utilization of the proposed PET service by Sumner & Macon County residents is noted. The projected increase in the "capture rate" (from 35% to 49% of 620 PET scans by residents of the PSA) appears to lead to a 40% increase in utilization from 241 procedures in Year 1 to 337 procedures in Year 2. What are the key factors that will determine whether or not the capture rate methodology is attainable?

9. Section C, Economic Feasibility Item 1 (Project Costs Chart) and Item 2 (funding)

Item 1- the following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the \$1,498,728.00 fixed equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

Item 2 - Cash reserves are noted in the response, please confirm that this will serve as the source of the "sufficient resources" noted in the CFO's 9/9/14 letter.

10. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

Are the costs for professional fees related to image interpretation services included in the Chart? Please identify the amounts that apply to the project in Year 1.

Review of the Income Statement (YTD ending December 2013) in the attachments revealed differences from the Historical Data Chart (2013 column) such that net income appears to be understated in the application by approximately \$4.4 million. Please clarify.

11. Section C., Economic Feasibility, Item 6 B.

The detailed comparison to HSDA Equipment Registry PET charges and Medicare allowable rates for selected applications is noted. It appears that the Medicare allowable charges (net charges) average only 14% of the applicant's average gross charge compared to 25%, on average, for all payors. What accounts for the higher net charge in the projected data chart?

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the projected Data Chart for the new service?

12. Section C, Economic Feasibility, Item 11 b.

The goals related to a more convenient and accessible site are noted. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the proposed outpatient campus that residents of the service area could expect?

What other key benefits should residents and their attending physicians be aware of in selecting SRMC's proposed PET service in lieu of other sites outside the service area?

13. Section C., Contribution to Orderly Development, Items 7 and 9

The copy of SRMC's licensure survey with plan of correction dated October 11, 2006 is noted. Review of the TDH website for licensed facilities revealed that SRMC's last survey was in June 2008. Please provide a copy of same with the provider plan of correction (POC) and a copy of acceptance of the POC by TDH for this survey.

14. Development Schedule

It appears that the earliest this application may be held with respect to the standard 60-day review cycle is December 17, 2014 in lieu of the November date entered on the form. Please revise the schedule.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60th) day after written notification is November 17, 2014. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the <u>next review cycle</u>, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. 3 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Jeff Grimm

Health Services Development Agency Examiner



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor

www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

September 26, 2014

Michael Herman Sumner Regional Medical Center Chief Operating Officer 555 Hartsville Pike Gallatin, TN 37066

RF

Certificate of Need Application CN1409-041

Sumner Regional Medical Center - Initiation of PET service on Outpatient Campus of Hospital

Campus of Hospi

Dear Mr. Herman,

This will acknowledge our September 25, 2014 receipt of your supplemental response regarding your application for a Certificate of Need for the initiation of a Positron Emission Tomography service (PET) on the hospital's existing outpatient campus at 225 Big Station Camp Boulevard, Gallatin (Sumner County).

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

<u>Please submit responses in triplicate by 1PM, September 30, 2014.</u> If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section B, Project Description, Item II.E. and Section C, Economic Feasibility, Item 1 (Project Cost Chart)

The revised quote extending the expiration date to 12/22/2014 and the revised Project Cost Chart for the addition of \$199,500 to the cost of the PET/CT unit for sales tax and freight are noted.

However, it appears that the Filing Fee in line E of the chart, should also have been revised as a result of the increase in the cost of the PET/CT unit. It appears that the new fee would amount to \$6,483, an increase of \$449. This change would also change the grand total in line F. Please remit the additional amount and provide a replacement page with the revised Project Cost Chart.

Given the 160 miles distance from the cyclotron to the proposed PET/CT location at Sumner Station, what is the life of the material that is required to account for driving times under normal conditions?

2. Section C, Need. Item 6

The clarification of the methodology used to determine the utilization of the proposed PET service by Sumner & Macon County residents is noted.

Is it correct that, given the higher projected capture rate in Year 3, that utilization, revenue, expenses and net operating income can remain as projected for Years 1 and 2 as identified in the Projected Data Chart? Please confirm.

3. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

<u>Historical Data Chart</u> - Thank you for the clarification and submission of the Revised Historical Data Chart.

In looking at same, it was noted that inpatient gross operating revenue increased by approximately 25% from \$178,940,000 in fiscal year 2012 to \$222,998,000 in FY2013. What accounts for this change when adjusted admissions only increased by approximately 4%during the period?

<u>Projected Data Chart</u> - What is the equivalent amount in procedures that ties to the projected charity cost of \$65,000 in Year 1 of the project (line C.3 of the chart)?

The \$115 per dose cost associated with the FDG/radioactive material and the 160 mile distance from the vendor's cyclotron in Louisville, Ky. is noted. What are the annual amounts for same that are included in the supply costs of the Projected Data Chart (line D.3)?

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." For this application the sixtieth (60th) day after written notification is November 17, 2014. If this application is not deemed complete by this date, the application will be deemed void. Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

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Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Jeff Grimm

Health Services Development Agency Examiner

COPY-SUPPLEMENTAL-1

Sumner Regional Medical Ctr. CN1409-041

BUTLER | SNOW



September 25, 2014 4:05pm

September 25, 2014

HAND DELIVERY

Jeff Grimm, Examiner
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE:

Certificate of Need Application CN1409-041

Sumner Regional Medical Center -

Initiation of PET Service on Outpatient Campus of Hospital

Dear Mr. Grimm:

Responses to the questions in your letter dated September 19, 2014, are below. The required affidavit is enclosed at the end of this response. Please let us know if you need additional information.

1. Section A, Applicant Profile, Item 3

There appears to be an error with the phone number listed for the owner.

Response: A corrected page 1-R is attached as <u>Attachment 1</u>.

The registration of the owner with the Tennessee Secretary of State's Office is noted. Please also provide a copy of the Corporate Charter or Partnership Agreement.

<u>Response</u>: The document titled Certificate of Formation included with the original application is the formational document for Sumner Regional Medical Center, LLC.

Describe the existing ownership structure of Sumner Regional Medical Center, LLC and identify the members of the LLC with 5% or more ownership interest.

<u>Response</u>: The sole member of Sumner Regional Medical Center, LLC, is LifePoint Hospitals.

The Pinnacle at Symphony Place 150 3rd Avenue South, Suite 1600 Nashville, TN 37201 DAN H. ELROD 615.651.6702 dan.elrod@butlersnow.com T 615.651.6700 F 615.651.6701 www.butlersnow.com

Jeff Grimm September 25, 2014 Page 2

SUPPLEMENTAL-1

September 25, 2014 4:05pm

2. Section B, Project Description, Item I

The executive summary is noted. Based on the hospital's accreditation by the American College of Surgeons, what recommendations from the review were made with respect to adding PET as a diagnostic & treatment planning modality to meet clinical standards of care?

<u>Response</u>: The subject of PET capability was not raised by the American College of Surgeons during its last accreditation review of SRMC, and SRMC does not believe that that PET capability is an aspect of the accreditation criteria

Review of HSDA records revealed that the applicant had a previously approved CON for a mobile PET service on the main hospital campus 1 day per month focusing on use for diagnosing neurodegenerative disease, cerebrovascular accidents, brain tumors and seizure disorders (CN0406-058A). The mobile PET service was not unimplemented and surrendered to HSDA in December 2007. If SRMC could not implement the mobile PET service approved in CN0406-058A, what has changed that it needs a fixed stationary PET unit for cancer diagnosis per this proposed project? Please discuss.

<u>Response</u>: The prior certificate of need was not implemented because of financial problems at SRMC that ultimately lead to the bankruptcy of the organization and purchase of it by LifePoint. With the financial strength of LifePoint, SRMC now has the resources to establish and sustain a fixed PET service as explained in the application.

3. Section B, Project Description, Item II.A.

There appears to be an error in the Square Footage Chart. The construction cost in SF Chart amounts to \$455,990 but should be revised to \$460,000 in order to be consistent with the \$322.80 per SF cost and the \$460,000 entered in line item 5 of the Project Cost Chart. Please clarify.

Response: A revised Square Footage Chart is attached as Attachment 2.

4. Section B, Project Description, Item II.C

The need for the proposed PET service based on the absence of a PET service in Sumner & Macon Counties is addressed here, in the executive summary and the project specific criteria on page 13. In addition to the recap of the TDH report on cancer in Tennessee, the applicant may wish to consult with a program representative of TDH's Tennessee Cancer Coalition to further support the need for the proposed service. If possible, please document the suggestions or recommendations discussed with the TDH representative.

<u>Response</u>: It appears that the Cancer Coalition is not currently operational. An SRMC representative's telephone call to the number on the Cancer Center website was answered with a recorded message that the number is no longer in service. Emails to the contact person on the Cancer Coalition's website have not been answered.

Jeff Grimm September 25, 2014 Page 3

SUPPLEMENTAL-1

September 25, 2014 4:05pm

The letter of support from Dr. Shipley, TN Oncology is noted, however, some estimate of referrals would be appreciated. Please provide letters from oncologists stating the estimated monthly PET referrals to SRMC.

<u>Response</u>: SRMC was unable to obtain letters with specific monthly estimates. As an alternative, SRMC is submitting at <u>Attachment 3</u> a letter from Dr. Shipley confirming the SRMC's projected volumes are reasonable. Tennessee Oncology is the only oncology group with a presence in Gallatin.

In addition to identifying services of the oncology program such as radiation therapy, surgery and chemotherapy services; please provide additional information about SMRC's oncology program that provides a brief description of hospital/medical staff organizational structures for coordinating the activities of the oncology program, including information systems such as its tumor registry and tumor board; and a description of how the proposed PET service can contribute to SRMC's participation in any clinical investigative protocols through formal oncology network relationships with other providers.

Response: Cancer care at SRMC is under the leadership of its cancer committee. The cancer committee is responsible for goal setting, planning, initiating, implementing, evaluating, and improving all cancer-related activities. The care of the cancer patients requires a multidisciplinary approach and encompasses numerous physician and non-physician professionals. Required physician members are a diagnostic radiologist, pathologist, general surgeon, medical oncologist, and radiation oncologist. Required non-physician members include the program administrator, oncology nurse, social worker or case manager, certified tumor registrar (CTR), performance improvement or quality management professional. Additional physician or non-physician cancer committee members are required for specific categories, such as a hospice/home care nurse or administrator, pain control/palliative care physician specialist and cancer clinical research data manager or nurse. Additional members of the committee from time to time may include individuals from various disciplines such as dietary, pharmacy, pastoral care, mental health, or the American Cancer Society.

The number and types of physicians on staff at SRMC involved in cancer care are as follows:

- Radiation oncologist 1 active staff; 10 coverage staff
- Medical oncologist 2 active staff; 16 consulting/coverage staff
- General Surgeons 4 active staff
- *Urologists 4 active staff*
- Radiologists 9 active staff
- Pathologists 4 active staff

Information regarding the Cancer Conference (Tumor Board) is set forth in Attachment 4.

Jeff Grimm September 25, 2014 Page 4

SUPPLEMENTAL-1

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Tennessee Oncology is involved in various clinical investigations. Dr. Shipley has advised that she is not aware of any immediate, primary use of the PET service for clinical trials, but she believes the service will be of benefit in connection with the detection of cancer cells, thus supporting clinical trials conducted for treatments.

5. Section B, Project Description, Item II.E.

Please note that the equipment quote for the base fixed unit cost of \$1,093,866 expired in August 2014. Please provide an addendum or updated quote from the equipment vendor such that the offer will be in effect on the date that the application will be heard by HSDA (December 2014 at earliest).

<u>Response</u>: The quote is dated August 29, 2014, but expires on November 21, 2014, which is the maximum time for which GE would provide a quote at the time. An updated quote effective through December 22, 2014, is attached as <u>Attachment 5</u>.

Please identify the costs associated with the FDG/radioactive material, and identify the terms of the contractual arrangement that might apply with supplier(s), as necessary (a copy of a draft agreement or letter of interest between the applicant and the vendor would be helpful). Please also identify the address and distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

<u>Response</u>: The cost of the radiopharmaceutical (FDG) used for PET scans is not a cost of the project, but is reflected as a supply cost in the Projected Data Chart. There is not initial investment or cost required to obtain these materials. Doses of FDG will be purchased on an as-needed basis when scans are scheduled.

The supplier for FDG to Sumner Station will be Cardinal Health located in Nashville, at a cost of \$115 per dose. Cardinal Health is a provider of nuclear medicines to LifePoint hospitals under a long-standing vendor relationship, as confirmed by the letter at <a href="https://dx.doi.org/10.1016/jhttps://dx.do

6. Section C. Need Item 1. (Project Specific Criteria – PET Service)

Item 2 - it appears that the first sentence would apply to the project (accessible to 75% of the population of Sumner and Macon Counties). Please describe how the proposed PET/CT unit at Sumner Station meets this criterion.

<u>Response</u>: Sumner and Macon counties constitute the primary service area for SRMC's other services, thus establishing that SRMC is accessible to the population. Sumner Station is in Gallatin; the other population center for Sumner County is Hendersonville, the center of which is about 10 miles from Sumner Station. The population of Lafayette, the population center for Macon County is about 35 miles from Sumner Station, but there is no other PET scanner closer than Sumner Station.

Jeff Grimm September 25, 2014 Page 5

September 25, 2014 4:05pm

Item 3 - it is noted the applicant considered the possibility of a mobile PET unit. Given the proposed utilization that is more characteristic of the criterion for mobile units plus the applicant's previous unimplemented CN0406-058AW, what factors would have to be met to make a mobile service more attractive?

<u>Response</u>: A fixed PET has obvious advantages in terms of patient convenience. In addition, SRMC believes that a fixed PET will more acceptable to patients and referring physicians. In light of the current cost of a fixed PET unit, it is also economically advantageous to SRMC to purchase a fixed unit rather than pay a mobile vendor for use of equipment that would not be an SRMC asset. The PET unit will be capable of serving patients well beyond the 5-year period of depreciation. A mobile unit would be more attractive only if a fixed unit was not economically viable.

Item 6.c. - It is noted the service will be operated as a part of SRMC on its outpatient campus and is subject to the same emergency plan & procedures. Since this is a new service, how will the applicant handle emergencies specific to the PET/CT? What are the responsibilities of the medical director or on-site physicians for same?

<u>Response</u>: In the event of an emergency, the staff at the facility will call for an ambulance for transport to SRMC. The physician on site will be able to evaluate the patient and administer life-saving techniques if necessary.

Item 6.g. - the name of the entity that has issued permits for CT services was omitted from the response. While it is understood that a permit would be premature – please list the key requirements that must be met. In your response, it may be helpful to include as an addendum with the 8/15/14 letter from the architect for the project.

<u>Response</u>: The entity referenced is the Tennessee Division of Radiological Health. The Radiation Safety Officer at SRMC is familiar with the Division's rules applicable to this project, specifically, Chapter 0400-20-07 <u>Standards for Protection Against Radiation</u> and Chapter 0400-20-07 <u>Use of Radionuclides in the Healing Arts.</u> Copies of these regulations are not included because of their length, but key points are as follows:

- The PET/CT room will need to be appropriately shielded (radiation protection is referenced in the attachment to the architect's letter, <u>Attachment C., Economic Feasibility 1</u> in the original application).
- The facility will require a hot lab (included in the floor plan, <u>Attachment B. IV</u> in the original application).
- A Radioactive Materials License from the Division will be required.
- SRMC will need to from a Radiation Safety Committee for Sumner Station, which will establish policies and procedures required by the regulations referenced above.
- SMRC will need to appoint a Radiation Safety Officer for the Sumner Station campus.

September 25, 2014 4:05pm

7. Section C, Need, Item 5

Please identify the use of PET providers in Davidson County and other areas of TN by residents of Sumner and Macon County for the most recent 3 years. A suggested template is the table below showing utilization by Sumner residents. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

Response:

PET Utilization by Sumner County Residents, 2011-2013

Providers with PET Service	Provider Location	Distance from SRMC Sumner Station	2011	2012	2013	% Change '11-'13
Premier*	Davidson	26.5	47	**	12	(74.5)%
Imaging Alliance	Davidson	30.0	268	296	297	10.8%
TN Oncology	Davidson	27.7	274	246	234	(14.6)%
Centennial	Davidson	26.8	18	14	20	1.1%
VUMC	Davidson	27.0	93	131	120	29%
All other TN providers	Statewide		31	21	20	(35.5)%
Total – TN			731	708	703	(4)%

^{*}Formerly Saint Thomas Midtown

8. Section C, Need. Item 6

Please summarize the strategies being implemented by SRMC other than the proposed relocation of the service that might help SRMC reach the 1,000 minimum utilization standards at some point within 5 years following project completion in October, 2016.

Response: The current PET market for Sumner and Macon is substantially below 1,000 scans annually, and it is uncertain if the volume of 1,000 scans per year will be achieved in the foreseeable future. However, SRMC notes that recent developments will likely lead to increased PET volumes. In 2013, CMS changed its coverage rules for PET, as summarized in Attachment 7. Specifically, there is now unconditional coverage for PET for 8 types of cancers for which special coverage determinations had to be made previously, and coverage is now approved for up to 3 PET scans for management of cancer involving anti-tumor treatment strategies. In any event, SRMC is proposing PET to complement existing cancer services and to make first-class diagnostic services conveniently accessible to patients in the community. SRMC has the resources to establish the service and the circumstances fit the criteria on the State Health Plan for special consideration.

Please identify the projected payor mix for the service in Year 1 as to # procedures and estimated gross revenue by payor in Year 1.

Response:

^{**}No data reported

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	Scans	Gross Revenue
Medicare	109	\$817,500
TennCare	16	\$120,000
Commercial	108	\$810,000
Self-pay	8	\$60,000

The methodology discussed on page 18 that identifies the utilization of the proposed PET service by Sumner & Macon County residents is noted. The projected increase in the "capture rate" (from 35% to 49% of 620 PET scans by residents of the PSA) appears to lead to a 40% increase in utilization from 241 procedures in Year 1 to 337 procedures in Year 2. What are the key factors that will determine whether or not the capture rate methodology is attainable?

Response: The original application incompletely and inaccurately explains SRMC's assumptions regarding a 2 year ramp-up period. The PET market for Sumner and Macon counties averaged a total of 714 scans annually over the past 3 years. SRMC expects its portion of the PET market in Sumner and Macon counties ultimately will be similar to its portion of the radiation therapy market (49%). 49% x 714=350. Assuming that 90% of the proposed scans will come from Sumner and Macon counties, the total expected PET volume at Sumner Station is 389. However, SRMC projected 241 scans in year 1 and 337 in year 2 to account for an extended ramp-up period, with the belief that it will achieve at least 49% market share in years 3 and beyond. The projections are conservative because they do not reflect likely increased volumes resulting from recent CMS coverage changes as referenced above. It should be noted that SRMC believes the assumption of 90% of scans from Sumner and Macon counties is also conservative, and it likely does not reflect the total potential for patients who reside in other counties but for whom Sumner Station is convenient.

9. Section C, Economic Feasibility Item 1 (Project Costs Chart) and Item 2 (funding)

Item 1 - the following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states "The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the \$1,498,728.00 fixed equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

Jeff Grimm September 25, 2014 Page 8

September 25, 2014 4:05pm

<u>Response</u>: The cost of the PET unit in the original application included the cost of equipment (\$1,093,866) and cost of maintenance for the first 5 years (\$404,862). There are no installation charges. However, the application did not include sales tax and freight charges, which total \$199,500. A revised Project Cost Chart is attached at <u>Attachment 8</u>. The applicant notes the total cost of the unit is below the dollar threshold of \$2 million to be classified as "major medical equipment."

Item 2 - Cash reserves are noted in the response, please confirm that this will serve as the source of the "sufficient resources" noted in the CFO's 9/9/14 letter.

Response: Yes.

10. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

Are the costs for professional fees related to image interpretation services included in the Chart? Please identify the amounts that apply to the project in Year 1.

<u>Response</u>: SRMC will not bill for, nor receive, professional fees. These services are billed separately by the radiologists.

Review of the Income Statement (YTD ending December 2013) in the attachments revealed differences from the Historical Data Chart (2013 column) such that net income appears to be understated in the application by approximately \$4.4 million. Please clarify.

<u>Response</u>: In the course of responding to this question, SRMC realized that it had included the incorrect Historical Data Chart that includes a small amount of non-hospital activity. A corrected Historical Data Chart is included as <u>Attachment 9</u>.

The difference of approximately \$4.4 million in 2013 net operating income in the corrected Historical Data Chart (\$6,406,000) and net income in the 2013 financial statement (\$10,647,021) is attributable to the following:

- The Historical Data chart includes \$4,152,000 for federal income taxes that are not in the internal financial statement because FIT is paid at the parent level. SRMC elected to include federal taxes in the Historical Data Chart as a more accurate representation of SRMC's financial results
- The Historical Data Chart does not include a one-time positive adjustment to income from rent in the amount of \$1,843,000, which is included in the financial statement. This item was excluded from the Historical Data Chart because it was a one-time adjustment and excluding it is consistent with historical consistency.
- The Historical Data Chart does not include interest as an expense, whereas the financial statement includes an interest expense allocation of \$1,754,000. SRMC elected not to include this allocation in the Historical Data Chart because it is not related to debt incurred by SRMC, but is an allocation of interest by the parent organization not reflective of financial results at SRMC.

Jeff Grimm September 25, 2014 Page 9

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11. Section C., Economic Feasibility, Item 6 B.

The detailed comparison to HSDA Equipment Registry PET charges and Medicare allowable rates for selected applications is noted. It appears that the Medicare allowable charges (net charges) average only 14% of the applicant's average gross charge compared to 25%, on average, for all payors. What accounts for the higher net charge in the projected data chart?

<u>Response</u>: SRMC's proposed charge of \$7,500 is based on pricing for PET services in LifePoint hospitals in other states that have fixed PET units. SRMC notes that the HSDA equipment registry data reflects considerable variability in PET charges in Tennessee. For example, charges for PET at TriStar Centennial in 2013 averaged \$14,928 per scan, charges at Premier Radiology Midtown averaged \$8,499 in 2013 and charges at Vanderbilt averaged \$4,834.

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the projected Data Chart for the new service?

<u>Response</u>: Radiologists will bill for and receive their fees for interpretation services. These fees are not part of the project.

12. Section C, Economic Feasibility, Item 11 b.

The goals related to a more convenient and accessible site are noted. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the proposed outpatient campus that residents of the service area could expect?

<u>Response</u>: The vast majority of patients in Sumner and Macon counties currently travel to one of the 5 Nashville providers. Most residents of Sumner County would experience a one-way drive of 25-30 miles that could require anywhere from 30-45 minutes depending on traffic. Most residents of Macon County now travel 60-70 miles one way to a Nashville provider, requiring 60-90 minutes depending on traffic. It should be noted that a significant proportion of cancer patients are over 65, and travel is burdensome to these patients, particularly travel to and in a large city like Nashville

What other key benefits should residents and their attending physicians be aware of in selecting SRMC's proposed PET service in lieu of other sites outside the service area?

<u>Response</u>: Patient convenience is the primary consideration. In addition, utilization of the PET at Sumner Station will contribute to SRMC's ability to maintain and evolve services in the community, thus making it possible for residents to receive more of their care closer to their homes.

13. Section C., Contribution to Orderly Development, Items 7 and 9

The copy of SRMC's licensure survey with plan of correction dated October 11, 2006 is noted. Review of the TDH website for licensed facilities revealed that SRMC's last

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survey was in June 2008. Please provide a copy of same with the provider plan of correction (POC) and a copy of acceptance of the POC by TDH for this survey.

<u>Response</u>: The survey in June of 2008 occurred before SRMC's bankruptcy and acquisition by LifePoint. LifePoint has been unable to find its copy of the June 2008 survey and POC; however, SRMC was able to obtain from the Division of Health Care Facilities a copy of the survey. The Division could not locate a copy of SRMC's POC, but the Division provided copies of its Revisit Report forms, which confirm all cited deficiencies were corrected. Copies of the survey and Revisit Report documents are attached as <u>Attachment 10</u>.

14. Development Schedule

It appears that the earliest this application may be held with respect to the standard 60-day review cycle is December 17, 2014 in lieu of the November date entered on the form. Please revise the schedule.

Response: A revised schedule is included as Attachment 11.

Very truly yours,

BUTLER SNOW LLP

clw Attachments

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF David Son

NAME OF FACILITY:	comper	Region	, Me	died	Center
I, An HEIrol applicant named in this Cer have reviewed all of the sur accurate, and complete.	tificate of Nee	ed application	or the law	ful agent th	nereof, that I
		Signatu	/// ure/Title		
Sworn to and subscribed befo witness my hand at office in th	ore me, a Notar ne County of	y Public, this t Pavid Sov	he <u>25</u> da L	ay of Sep _, State of T	<u>2∱,</u> , 20 <u>/4</u> , Γennessee.
	Zastra RON	NOTAF	harron RY PUBLIC	c.C.C	Touch
My commission expires HF-0043	TENNE NOT/ PUB	SSEE ARY	— ₹		
Revised 7/02	My Commission Ex	pires MAR. 8, 2016			

September 25, 2014 4:05pm

Attachment 1

1.	Name of Facility, Agency, or Institution Sumner Regional Medical Center (for		anue)	September	25, 201 4:05pr
	Name	its Summer Station Can	ipus)	<u> </u>	
	225 Big Station Camp Road		Sun	nner	
	Street or Route		Col	unty	
	Gallatin	TN	370	066	
	City	State	Zip (Code	
2.	Contact Person Available for Respon	nses to Questions			
	Michael Herman	Chief	Operating O	fficer	
	Name		Title		
	Sumner Regional Medical Center	Michael.l	Herman@LPI	NT.net	
	Company Name		Email addre		
	555 Hartsville Pike	Gallatin	TN	37066	
	Street or Route	City	State	Zip Code	
	COO	615-328-6695			
	Association with Owner	Phone Number	Fax	Number	
3.	Owner of the Facility, Agency or Inst	titution			
	Sumner Regional Medical Center, LLC	:	615-920-7	000	
	Name	·	Phone Nui		
	330 Seven Springs Way		Sum	ner	
	Street or Route		Cou		
	Brentwood	TN	37027	•	
	City	State		Code	
	See <u>Attachment A, Item 3</u>		·		
4.	Type of Ownership of Control (Chec	k One)			
	A. Sole Proprietorship B. Partnership C. Limited Partnership D. Corporation (For Profit) E. Corporation (Not-for-Profit)		ure ability Compai		<u> </u>
	See Attachment A, Item 4				

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

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Attachment 2

	Total	\$455,990				Kow Ball									P. 3 (1) 5 (5)		Sep	\$460,0	ber 25, 2014 4:05pm
Proposed Final Cost / SF	New								STATE OF STATE			100							
	Renovated	\$322.80								表記のもでは								\$460,000	
	Total	1,425																1,425	
Proposed Final Square Footage	New															Included	Included		
Pr Sq	Renovated	1,425														Included	Included	1,425	~
Proposed Final	Location	Sumner Station																	7-R
Temporary	Locallori	ĵ																1000	
Existing	L O																		
Existing	Localion																		
A. Unit / Department														B. Unit/Depart. GSF Sub-Total		C. Mechanical/ Electrical GSF	D. Circulation /Structure GSF	E. Total GSF	22733669v1

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART

7-R

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Attachment 3

September 25, 2014 4:05pm

TENNESSEE ON COLOGY

www.tnoncology.com

MEDICAL ONCOLOGY/ HEMATOLOGY

Dianna L. Shipley, M.D. Mathew J. Joseph, M.D.

Amy Cox, APRN-BC, AQCNP Cyndi M. Adair, ACNP-BC

Re: Proposed PET at Sumner Station

Dear Mike:

This will confirm our recent conversation regarding the certificate of need application filed by Sumner Regional to implement PET service at Sumner Station.

As you know Tennessee Oncology is the largest oncology group in Middle Tennessee and we serve more cancer patients in the region than any other group of physicians. We are the only oncology group with a presence in Gallatin.

It is my understanding that your planning for the PET service at Sumner Station assumes that your percentage of PET volumes from the Sumner County and Macon County market will be approximately the same as the percentage you currently have of the market for radiation therapy in the area, which is about 50%. Based on my knowledge of the services and patients in the market, I believe your assumption is valid, and I would expect that the PET service at Sumner Station would ultimately serve at least 50% of the patients from the region who need PET.

I hope this letter is helpful to your application.

Sincerely,

Munna Shipley, M.D.

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Attachment 4

September 25, 2014 4:05pm

Sumner Regional Medical Center Cancer Program

TITLE: CANCER CONFERENCE (Tumor Board)

POLICY: To provide routine multidisciplinary collaboration between clinicians for the purpose of providing comprehensive management for the oncology patient.

Sumner Regional Medical Center's Cancer Committee has approved cancer conferences to be held monthly. Cancer Conferences are integral to improving the care of cancer patients by contributing to the patient management process and outcomes and providing education to physicians and other staff in attendance.

Conference is available to all medical staff personnel and Allied Health personnel. Required attendance at conference is physicians responsible for the site being presented along with medical and radiation oncology, radiology, pathology, surgery and medicine.

PROCEDURE:

- The managing physician selects cases based on clinical importance from cases currently being managed. Case presentations include patients recently seen in consultation as well as patients being actively managed as an inpatient or on an outpatient basis.
- Cancer Registry personnel are responsible for coordinating and maintaining cancer
 conference documentation. Cancer conferences are scheduled in advance. A yearly
 calendar of scheduled conference dates is to be completed by the end of November as
 well as reserving meeting room.
- The number of cases discussed is proportional (15 % of annual analytic caseload)
- 15% of our annual analytic case load will be presented at cancer conference with 75% of these cases being prospectively.
- Discussion will include:
 - 1. Review of clinical evaluation, i.e., diagnostic imaging studies and pathology
 - 2. Appropriate case management based on clinical presentation and extent of patient's disease, performance status, and co-morbidity
 - 3. Accurate AJCC stage (either clinical stage or working stage) or other appropriate stage
 - 4. National Comprehensive Cancer Center Network (NCCN) treatment guidelines or other treatment guidelines developed by nationally recognized organizations, such as the American Cancer Society of Clinical Oncology (ASCO), should be considered when discussing treatment options where appropriate.
 - 5. 90% of all Physicians required to attend must meet this percentage. Medical Oncology, Radiation Oncology, Radiology, Pathology, Surgery and Cancer Registry.
 - 6. A conference grid is maintained by the Cancer Registry to accurately monitor conference frequency (monthly), multidisciplinary attendance, total case presentation, the rate of prospective cases presentation, Options for clinical trial participation.

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- 7. Conference grid includes documentation of the fact that AJCC staging or other appropriate staging was discussed, where appropriate.
- 8. Cancer Conference activities are reported by the Cancer Conference Coordinator to the Cancer Committee at least quarterly.

Conference documentation includes:

- 1. Date of meeting
- 2. Sites discussed/Prospective-retrospective
- 3. Physician attendance
- 4. Non-physician attendance
- 5. Clinical Staging and National Treatment guidelines reviewed and care plan consistent with guidelines
- 6. Eligible for clinical trials
- 7. Agenda for Cancer Conference provided to physicians

DISTRIBUTION:

Cancer Program

APPROVAL:

Cancer Committee

REVIEWED:

01/03; 01/05; 01/06; 02/07, 2/08, 2/10,2/14

REVISED:

1/04, 01/09

ORIGINAL:

2002

Cancer Program Policy and Procedure Manual

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Attachment 5

SUPPLEMENTAL-1

QUOTATION September 25, 2014 4:05pm

Quotation Number: PR5-C23806 V 5

Sumner Regional Medical Center LLC 555 Hartsville Pike

Gallatin TN 37066-2400

Attn: Frank Givens

Director of Radiation Oncology

Radiation Oncology 555 Hartsville Pike Gallatin TN 37066 Date: 09-24-2014

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"), "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if ony) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

• Terms of Delivery:

FOB Destination

• Quotation Expiration Date:

12-22-2014

• Billing Terms:

80% on Delivery/ 20% on Acceptance or First Patient Use

financing.

• Payment Terms:

NET 30

• Governing Agreement:

LifePoint Corporate Services

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare

3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Bryan Fondrie
09-24-2014

Product Sales Specialist

US Phone: +1 262 352 1354 Fax: 414-918-8543

Bryan.Fondrie@ge.com

CUSTOMER

Authorized Customer Date

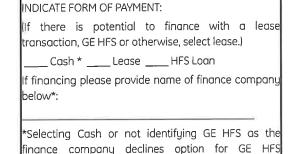
Print Name and Title

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PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually



1/27



GE Healthcare Confidential and Proprietary General Electric Company, GE Healthcare Division 3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

SUPPLEMENTAL-1

QUOTATION September 25, 2014 4:05pm

Quotation Number: PR5-C23806 V 5

agreed upon by the parties.



QUOTATION September 25, 2014 4:05pm

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
,	1		Optima PETCT 560			
1	1	S9216OB	Powerful and versatile, the Optima PET/CT 560 is an all-around remarkable scanner designed to meet the demands of today's mainstream clinical imaging environment.	\$2,250,000.00	58.48%	\$934,107.24
			It's a scanner we built both for you and around you, by combining superb image quality, high productivity, and a patient friendly experience. All in a system that can continuously deliver ongoing value for you over time, while helping you maintain high standards of patient safety and care.			
			An integrated gantry combined with the PET/CT operator console, enables fully integrated PET/CT scanning, processing, review and data management.			
			The GE Optima PET/CT 560 consists of			
			o One integrated gantry containing a BrightSpeed Elite CT with Performix Ultra Metal Ceramic X-Ray tube and 16-slice detector, 24 PET detector rings of bismuth germinate (BGO) crystals, high-speed electronics and PET image reconstruction system.			
			o One patient imaging table, one head holder, patient security straps and comfort accessories.			
			Prospective Reconstruction			
			o VUE Point HD utilizes a fully 3D iterative reconstruction technique with all corrections within the loop, enhanced resolution with detector geometry modeling, model-based 3D scatter correction inside and scatter			



QUOTATION
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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		estimation outside the field of view, exclusive randoms corrections based on singles and dead-time correction with pile-up estimates providing high image quality and patient throughput.			
		Calibration and Daily Quality Control			
		Daily Quality Assurance at the start of the scanning day is quick and efficient. A single button push launches the DQA procedure, which takes less than 10 minutes and provides you with a daily report. All of this with no additional radiation exposure to your technologists thanks to our automated source loader.			
		Automated PET calibration and QC with self shielded robotized calibration source handling system provides fast start up and lower dose to staff with documented and reproducible daily QC.			
		Power Management			
		o Energy Save Mode * Place the console, PET computers, and gantry into a sleep mode such that non essential electronics minimize energy usage and heat generation resulting in electricity savings for the facility.			
		PET Reconstruction			
		Fast reconstruction times deliver images to you sooner, allowing decision making before your patient is even off the table. Powerful GE reconstruction technology prospectively creates 3D iterative images from massive PET/CT data sets at incredible speeds.			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		CT Features			
		Your Optima PET/CT 560 can be operated as a standalone 16-slice CT scanner. With its exceptional power, remarkable speed, high resolution/low-dose imaging,and full diagnostic capabilities, it can help increase your patient imaging volumes and revenues.			
		The Optima PET/CT 560 includes the GE BrightSpeed Elite 16 slice CT that can perform a wide variety of clinical applications not requiring gantry tilt and has the following features Technology			
		o 0.625mm FWHM at Helical: Helical reconstruction technologies, crossbeam correction, conjugate ray interpolation and hyper plane helical reconstruction with alpha smoothing method allow Scan Thin 0.625mm, and Recon Thin 0.625mm.			
		o Performix* tube provides high power for multi-organ acquisition, sub-millimeter slice thicknesses and sub-second scanning. SmartTube* technology adapts to clinical needs to improve longevity and reliability.			
		o Short gantry geometry offering high X-ray efficiency, in conjunction with hyper generator			
		and the Performix Ultra X-ray tube delivers up to 440mA and seamless throughput			
		o Volara* Digital DAS, Data Acquisition System, with an increased sampling rate of up to 20% and noise reduction			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		up to 33%, results in outstanding image quality in signal-starved areas (shoulder, hip, large patient, metal).			
		o With an optimized beam, the Optima PETCT 560 with BrightSpeed Elite reduces the dose even without post-patient collimation. With post-patient collimation, one half of the beam never reaches the detector, resulting in wasted dose. In GE's BrightSpeed, the beam narrows before entering the patient, reducing the dose and optimizing the beam for image generation. Dose Management			
		o 3D mA modulation acquisitions may reduce dose compared with fixed mA acquisitions. mA modulation is designed to optimize the dose for the user prescribed noise index. It's effect on dose depends on the patient body habitus, and prescribed noise setting.			
		o ECG Dose Modulation: prospective ECG dose modulation automatically adjusts the mA to reduce dose during systolic phases of the cardiac cycle.			
		o Winner of a National Heroes Award from the Emergency Medical Services for Children, provides pediatric scan protocols based on the Broselow-LutenTM Pediatric System. This Color Coding system is incorporated into the protocol selection on the operator's console and is designed to facilitate pediatric emergency care and reduce medical errors			
		o Dose report: In conjunction with prospective display of CTDIvol, DLP			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		and dose efficiency,dose report helps clinicians reach ALARA dose, and keep track of it. Report is available in both DICOM secondary capture and structured report format.			
		o Dose Check: Provides the user tools to guide dose given in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA). Dose Check provides the following: Checking against a Notification Value if the estimated dose for the scan is above your site typical dose value, checking against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters, defining Alert Values for Adult and Pediatric with age threshold, audit logging and review, protocol change control			
		PET/CT Operators Console o Fully integrated PET and CT user			
		interface			
		o Direct Multi Planar Reformat delivers automated axial, sagittal, and coronal reconstruction with excellent image quality for PET and CT images of the patient data being acquired. Direct3D TM automatically builds 3D models during axial image reconstruction.			
		o Volume Viewer: Environment for 3D processing of any CT, MR, 3D X-ray, and Pet/CT dataset.It provides exceptional tools for analysis,			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		segmentation, measurements, annotation, filming, and exporting of clinically relevant images. Volume Viewer seamlessly combines anatomical image review with PET quantitative measurement capabilities such as SUV.			
		o Freedom Workspace*: Innovative hardware and software creates a convenient, ergonomic working environment. It offers sit/stand and horizontal/vertical monitor flexibility.It can also help reduce noise and heat with remote location of the console.			
		o Two 19 -inch diagonal width high-resolution color monitors for image display, analysis, processing, and management of PET, CT, and PET/CT images.			
		o Three button mouse with mouse pad			
		o 6 frames per second CT reconstruction at full resolution with optional 16 frames per second.			
		PET/CT Service Features			
		Each system is supported by GE's InSite TM remote diagnostics, iLinq TM, and TiP Virtual Assist.			
		InSite broadband * all hardware and software required to remotely connect this PET/CT system to GE's InSite On-Line Center via secure VPN high-speed Internet connections. Enables access to services designed to reduce downtime, improve quality, enhance performance, increase productivity, and expand imaging			



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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			capabilities with increased privacy and security of data transmissions.			
			Available for quoting but may not be booked until Regulatory approval has been obtained from the appropriate authorities in the local country.			
2	1	S9100YT	Discovery* PET/CT 600/610 NaF-18 PET Promotion:	\$100,000.00	58.48%	\$41,515.88
			This promotion includes advanced PET features designed to enable improved image quality and workflow for NaF-18 PET studies:			
			SharpIR:			
			Advanced system modeling in PET reconstruction that enhances visual contrast and resolution in both whole-body and brain images by incorporating resolution modeling within the iterative reconstruction.			
			On/Off capability allows use of the reconstruction method on all studies or only those chosen, maintaining longitudinal quantitative accuracy.			
			2 Meter Scan Option:			
			The system can perform a full 2 meter acquisition of both CT and PET data, through the use of a cradle extender and specific acquisition protocols.			
			RadRx Kit:			
			Automatically combine various CT techniques within the same acquisition session, and use them for PET attenuation correction.			
			Average Cine CT reduces the impact of attenuation correction mismatches. It			



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item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			provides better quantitative accuracy with significant difference in SUV measurements from non-Average Cine CT.			
			Connect Pro - Offers New Levels of Productivity by providing a Connection Between the Facilities Hospital (HIS) or Radiology (RIS) Information System. ConnectPro Simplifies and Eliminates Errors in Patient Data Entry.			
			Exam Split - Provides the capability to "split" a series of patient images into separate groups that can be networked to desired reading stations for multiple "reads" and multiple			
			billings on select patient exams. Using the Exam Split option will allow for split images from a single acquisition and assign them to a Requested Procedure ID or accession number retrospectively.			
3	1	S5052MO	ASIR	\$175,000.00	58.48%	\$72,652.79
			Available on Discovery PETCT 610 and Discovery PETCT 710 with BrightSpeed Elite			
			Adaptive Statistical Iterative Recon (ASIR) provides users with a an innovative image reconstruction technology to reduce unwanted noise in diagnostic CT images, allowing users to improve image quality at up to 40 percent less dose.			
			ASIR feature name is licensed for use with a GE X-ray tube. Use of a third party x-ray tube will require purchase of an additional license for these features.			



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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
4	1	P5051TF	Long length cable set for Discovery PET/CT 16sl products	Incl.	Incl.	Incl.
5	1	B7877BC	USB Bar Code reader for use with ConnectPro (optional) Connect Pro - Offers New Levels of Productivity by Providing a Connection Between the Facilities Hospitial (HIS) or Radiology (RIS) Information System. ConnectPro Simplifies and Eliminates Errors in Patient Data Entry.	\$1,000.00	58.48%	\$415.16
6	1	B77292CA	Service cabinet for system accessories storage	Incl.	Incl.	Incl.
7	1	B77322CA	CT CHAIR NO ARMREST	\$721.46	58.48%	\$299.53
8	1	P5051LZ	WideView software option for Discovery ST/STE	\$50,000.00	58.48%	\$20,757.94
			PET/CT-WFOV increases the maximum CT display field of view from 50 cm to 70 cm. This dramatiC increase provides clinicians additional anatomical reference for large patients or radiation therapy simulation and planning.			
			Pre-requisite: Discovery Dimension Console			
			Invoice disclaimer - If the product is purchased as part of a combined package the total discount should be apportioned among each product in the package for accounting and reporting purposes.			IX.
9	1	E6315JE	DIACOR RTP Flat Tabletop for CT and PET/CT Systems- RT16, DVCT, Discovery PET/CT 600, 610, 690, 710, HD750, and VCT	\$15,000.00	21.00%	\$11,850.00
			Diacor Radiation Therapy Planning			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
		Overlay For GE Healthcare Global Tables, Model 1700, 2000 and PET/CT			
		The Radiation Therapy Planning Overlay, or "CT Overlay", provides a secure flat surface for CT Simulation applications, consistent with the treatment couch, for accurate and reproducible patient positioning.			
		FEATURES/BENEFITS			
		o Carbon fiber construction with foam core provides durable, light-weight device with outstanding imaging properties o Varian Exact Technology and Indexing Immobilization Patient Positioning system along entire length of the overlay o Designed specifically for GE Healthcare's Global Table o Easily locks and unlocks from the CT Table, providing easy transition between therapy and diagnostic procedures	a		
		INCLUDED:			
		o Carbon Fiber CT Overlay with locking accessories o Two Varian Exact Couch Indexing Bars o One Varian Respiratory Gating Interface Plate and associated mounting hardware			
		SPECIFICATIONS:			
		Weight: 30 lbs. (13.61 kg) Length: 85.25 in. (217.17 cm) Width: 20.87 in. (53.0 cm) Height: 1.62 in. (4.12 cm)			
10 1	E4502F	3 Phase 14 KVA Partial UPS for Lightspeed VCT, Discovery ST - HP and Lightspeed Pro32.	\$27,000.00	21.00%	\$21,330.00
		The 14KVA Partial UPS has been specifically designed to coordinate			



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Item No. Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price

with GE Healthcare CT & PET/CT scanners. In the event of a power outage a partial system UPS provides continuous backup power to the scanner host and control computers, thus assuring no loss of usable scan data. In addition, critical circuits in the gantry and table remain powered which facilitate the safe removal of the patient from the scanner. If power is restored within the battery hold-up time, the operator can continue scanner operations without the need to reboot the system. When longer power outages are anticipated, the UPS provides time for the operators to safely remove the patient and complete an orderly shutdown of the system software.

FEATURES/BENEFITS

- True double-conversion, online technology provides reliable operation & uninterrupted glitch free power
- Automatic voltage and frequency selection eases startup, i.e., 50 or 60 Hz compatible
- Integral Manual Bypass switch facilitates continued scanner operation while UPS is being serviced
- Single input connection utilized for both UPS input and static switch
- Maintains system electronics and allows critical scanner operations to continue for > 10 minutes (typical) after loss of



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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			 power Protects electronics from under voltage, brownouts, line sags, over voltage and transients Advanced Battery Management (ABM) software monitors / indicates battery health and improves battery service life 			
			SPECIFICATIONS			
			 Dimensions (H x W x D): 49" x 12" x 32" Weight: 620 lbs. Rating: 14.4 kVA Input Voltage Range: Three-Phase; 102-132V / ph Input Frequency Range: 45-65 Hz Output Frequency: 50 or 60 Hz, auto-sensing COMPATIBILITY CT LightSpeed Pro 32, Lightspeed VCT, CT 750HD, PET Discovery ST & ST-HP, PET Discovery VCT, PET 			
			Discovery 600/690 NOTES:			
			 Customer is responsible for rigging and arranging for installation with a certified electrician ITEM IS NON-RETURNABLE AND NON-REFUNDABLE 			
11	1	E4502AB	90 Amp Main Disconnect Panel for CT	\$7,349.00	21.00%	\$5,805.71
			This 90 amp main disconnect panel for GEHC CT systems provides emergency shut down, undervoltage protection,			



SUPPLEMENTAL-1

QUOTATION September 25, 2014 4:05pm

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			overcurrent protection, local disconnect for the imaging system. It also reduces installation time and cost by providing a single-point power connection eliminating the need to mount and wire a number of individual components. The standardized design and testing assures high product quality and system reliability, and it is UL and cUL listed for compliance with National Electric Code. Panel can be surface or semi-flush mounted and includes one remote emergency off push button. Customer is responsible for rigging and arranging for installation by a licensed electrician. ITEM IS NON-RETURNABLE and NON NON-REFUNDABLE Warranty Code: Y			
12	1	E8690AF	Discovery PET/CT 600/610 Pin Source The PET/CT 600/610 Pin Source is a GE-68 line source used to provice necessary calibration of the PET gantry. The line source is also used as a reference standard to perform automated daily quality assurance.	\$8,000.00	21.00%	\$6,320.00
13	1	E8500NB	Patient Arm Support for NM, PET/CT, MR Padded Arm Rest combines total arm support and passive restraint, increasing patient comfort during extended procedures. Designed to accommodate virtually all patients. Compatible with most Nuclear Imaging systems and can also be used in MRI, CT and PET applications. Constructed with a comfortable, full support polyfoam with a seamless coated finish. Warranty Code: H	\$675.00	21.00%	\$533.25



SUPPLEMENTAL-1

QUOTATION September 25, 2014 4:05pm

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
14	1	E8008P	VQC Phantom	\$3,500.00	21.00%	\$2,765.00
			Quality Control Phantom for Volumetric Registration.			
15	1	E8000HF	2 TB USB External Hard Drive	\$650.00	21.00%	\$513.50
			Provides a user-accessible means of transferring list data to alternative storage, to permit keeping the data while freeing scanner resources for additional patients.			
			The USB external hard drive will provide storage of 2 terabyte and interface with GE Healthcare Global Operator Consoles via USB 3.0 interface that provides up to 10 times faster data transfer rates compared to USB 2.0 interfaces.			
			USB 3.0 is backward compatible with USB 2.0			
			Quote Summary:			
			Total Discount: (57.60%)			(\$1,520,029.46)
			Total Extended Selling Price: Customer Loyalty Discount			\$1,118,866.00
			Total Quote Net Selling Price			\$1,093,866.00
			(Quoted prices do not reflect state and lo Trade in allowance, if applicable.)	ocal taxes if applicable	e. Total Net Selling	g Price Includes



September 25, 2014 4:05pm

Attachment 6

210 25th Asseptember 25, 2014 Nashville, IN 37203 615-327-3356 (phone) 615-320-0431 (fax)



September 23, 2014

To whom it may concern:

Jui me

Cardinal Health will provide unit dose F-18 FDG doses to Sumner hospital and any of its affiliates according to the Healthtrust Purchasing Group contract available to any Lifepoint facility per Lifepoint's signed agreement with Cardinal Health. The current contract price is \$115 per unit dose.

Sincerely,

Kevin Marsh

September 25, 2014 4:05pm

Attachment 7

GE Healthcare

September 25, 2014 4:05pm

Medicare National Coverage for Positron Emission Tomography (FDG) for Solid Tumors

Summary of the Coverage Policy

On June 11, 2013, the Centers for Medicare & Medicaid Services (CMS) posted a final national coverage decision (NCD) memorandum that announced two important coverage policy revisions for FDG PET for solid tumors:¹

- CMS will end coverage with evidence development (CED) that had previously been required for several cancer indications when using FDG PET to inform initial and/or subsequent Anti-tumor Treatment Strategies (ATS).
- CMS will cover three FDG PET scans when used to guide subsequent management of ATS after completion of initial anti-cancer therapy for any cancer indication. Additional coverage of FDG PET scans beyond the three scans will be determined by local Medicare Administrative Contractors (MACs).

The first coverage policy revision changes the following cancers from the status of "coverage with evidence development" to "covered": brain, cervix (uteri), small cell lung, soft tissue sarcoma, pancreas, testes, prostate,² thyroid, and all other cancers not specifically listed. Consequently, physicians will be

reimbursed for ATS PET studies for these cancers without having to supply data to the National Oncologic PET Registry (NOPR). This change reflects CMS's determination that current evidence is adequate to conclude that the results of FDG PET scans will guide physicians in managing the subsequent ATS of Medicare beneficiaries who have completed an initial treatment regimen. Table 1 summarizes CMS coverage policy for FDG PET studies for solid tumors.

The second coverage policy revision specifies the number of FDG PET scans that Medicare will cover to guide subsequent management of ATS for all solid tumor cancers. The revised national coverage policy allows for coverage of three FDG PET scans; however, CMS recognizes that a patient who has not been successfully treated with initial anti-tumor therapy might be a candidate for 'second line' or even further treatment, and there might be instances where additional FDG PET scans -- beyond three -- can be appropriately informative, depending on pertinent facts that can be found in the patient's medical documentation. For this reason, CMS will now permit local MACs to determine coverage for additional FDG PET scans beyond three that are automatically covered by this new policy.



Table	1. Changes in Medicare National Coverage for FD	G PET for Solid Tumors
	Before June 11, 2013	After June 11, 2013 4:05pm
Intellection	Colorado de la Colora	Initial Treatment Subsequent

	Before Ju	ne 11, 2013	After June 11, 2013 ember 2			
Tumor Type	Initial Treatment	Subsequent Treatment	Initial Treatment	Subsequent Treatment		
Colorectal	Cover	Cover	Cover	Cover		
Esophagus	Cover	Cover	Cover	Cover		
Head and Neck (not thyroid CNS)	Cover	Cover	Cover	Cover		
Lymphoma	Cover	Cover	Cover	Cover		
Non -small cell lung	Cover	Cover	Cover	Cover		
Ovary	Cover	Cover	Cover	Cover		
Brain	Cover	CED	Cover	Cover		
Cervix	Cover/CED ¹	Cover	Cover ²	Cover		
Small cell lung	Cover	CED	Cover	Cover		
Soft tissue sarcoma	Cover	CED	Cover	Cover		
Pancreas	Cover	CED	Cover	Cover		
Testes	Cover	CED	Cover	Cover		
Prostate	Non-cover	CED	Non-cover	Cover		
Thyroid	Cover	Cover/CED ³	Cover	Cover		
Breast (male and female)	Cover ⁴	Cover	Cover ⁵	Cover		
Melanoma	Cover ⁶	Cover	Cover ⁷	Cover		
Myeloma	Cover	Cover	Cover	Cover		
All other solid tumors	Cover	CED	Cover	Cover		
All other cancers not listed	CED	CED	Cover	Cover		

¹Nationally non-covered for diagnosis of cervical cancer. Covered for the detection of pre-treatment metastases in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are CED.

Implications for the National Oncology PET Registry (NOPR)

This national coverage policy revision removes the requirement for prospective data collection by the NOPR for those cancers or cancer types that had been covered under CED and are now listed as covered. That is, NOPR will no longer accept new FDG case registrations effective June 12, 2013. However, NOPR will still continue for NaF-PET which is addressed in a separate national coverage policy.3,4

Definitions

"National Coverage Determinations (NCD)" are developed by CMS to describe the nationwide conditions for Medicare coverage for a specific item or service.⁵ Once published, an NCD is binding on all Medicare Administrative Contractors (MACs) and Medicare Advantage (Part C) health plans.

"Local Coverage Determinations (LCDs)" are decisions published by local MACs on whether to cover a particular service in its regional jurisdiction.6 LCDs may be developed in

²Non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are covered.

³Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are CED.

^{*}Non-covered for diagnosis and/or initial staging of axillary lymph nodes. Covered for initial staging of metastatic disease.

⁵Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy are covered.

⁶Non-covered for initial staging of regional lymph nodes. All other uses for initial staging are covered.

Non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy are covered.

the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy.

"Coverage with Evidence Development (CED)" is a coverage decision made through an NCD.7 This type of NCD requires additional data collection (e.g., data collected in a clinical trial or registry) as a condition of coverage. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of its impact on the health of Medicare beneficiaries.

"FDG PET" refers to PET imaging utilizing FDG as the radioactive tracer (2-deoxy-2-[18F]-fluoro-D-glucose, also known as 18F fluorodeoxyglucose). CMS includes integrated FDG PET/computerized tomography (FDG PET/CT) and integrated FDG PET/magnetic resonance imaging (FDG PET/MRI) in the term FDG PET.

"Completion of initial anticancer therapy" denotes the conclusion of the first treatment regimen implemented for the elimination or control of a patient's cancer following its diagnosis. A treatment regimen could include multiple 'therapies' (such as chemotherapy, radiotherapy, and/or cancer surgery) in combination. The completion of initial anticancer therapy (that is, the conclusion or termination of all anticancer therapies in the initially intended (combination) treatment regimen) marks, in time, the starting point of subsequent ATS planning (and the completion of initial ATS planning). Note: CMS does not consider 'watchful waiting' as a therapy to be included in an initial treatment regimen.

Frequently Asked Questions

- Do Medicare revisions to its NCD for FDG-PET for cancer affect the reimbursement amount received by providers?
 - Answer: No. Coverage determinations specify the patient conditions, and diagnostic testing or treatment pre-requisites Medicare requires for a patient to qualify to receive an FDG-PET scan. Medicare reimbursement amounts are unchanged by revisions in coverage policies and are published in separate Medicare regulations.
- 2. Does the Medicare NCD for FDG-PET for cancer affect coverage by commercial payers?
 - Answer: No, not directly. Commercial payers have their own internal processes and criteria for making or revising coverage policies. However, most commercial payers monitor Medicare coverage decisions and some may be influenced by Medicare coverage policy decisions in the development or revision of their own policies.
- 3. How does the Medicare NCD for FDG-PET for cancer affect coverage of FDG-PET for cardiac or neurological conditions?
 - Answer: Medicare's NCD for FDG-PET for cancer does not impact coverage of FDG-PET for any other type of indication, e.g. cardiac or neurological. Medicare has separate coverage policies for these other indications.
- 4. Does the Medicare NCD for FDG-PET for cancer apply to combination PET technologies, such as PET/CT and PET/ MRI?

Answer: Yes. In this coverage decision, CSS includes 25, 2014 integrated FDG PET/computerized tomography (FDG PET/COMPUTER) and integrated FDG PET/magnetic resonance imaging 4:05pm (FDG PET/MRI) in the term FDG PET.

- 5. How does Medicare's NCD for FDG-PET affect reporting of PET scans to the National Oncology PET Registry?
 - Answer: The Medicare NCD for FDG-PET for Solid Tumors calls for the end of the prospective data collection requirements under CED for all oncologic indications for FDG-PET. Please note that this decision applies to the FDG-PET registry established in 2009 (NOPR-2009) only. Effective June 12, 2013, the NOPR-2009 registry will no longer accept new case registrations. However, the NOPR registry to study NaF-18 PET to identify bone metastasis of cancer will remain open.⁸
- 6. Who determines coverage for FDG-PET for Medicare patients with cancer who need more than three follow-up PET scans?

Answer: Local MACs have the discretion to determine whether additional FDG-PET scans (beyond three) are reasonable and medically necessary for Medicare patients who have cancer. The patient's physician will likely need to submit written documentation to the MAC to establish the medical necessity of the procedure for the particular patient circumstance.

¹CMS. Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4). June 11, 2013. http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=263 accessed 6/19/13.

²Prostate cancer remains non-covered for initial treatment strategy.

³CMS. National Coverage Determination (NCD) for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19). http://www.cms.gov/medicare-coverage-database/details/ncd-details. aspx?NCDId=336&ncdver=1&bc=AgAAQAAAAAAAAA3d%3d& accessed 6/19/13

⁴National Oncology PET Registry News. http://www.cancerpetregistry.org/ news.htm#June0112013 accessed 6/19/13

⁵CMS. Innovators' Guide to Navigating Medicare. 2010. pp. 11-13. http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf, Accessed 6/19/13.

⁵lbid.

7lbid.

⁹National Oncology PET Registry. NOPR Update: Closing of FDG PET Data Collection. (June 11, 2013). http://www.cancerpetregistry.org/news.htm

September 25, 2014 4:05pm

Attachment 8

PROJECT COSTS CHART

September 25, 2014 4:05pm

	_			4:05
A.	Con	struction and equipment acquired by purchase:		
	1.	Architectural and Engineering Fees		\$75,000
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees		\$47,000
	3.	Acquisition of Site		·
	4.	Preparation of Site		
	5.	Construction Costs		\$460,000
	6.	Contingency Fund		\$115,000
	7.	Fixed Equipment (Not included in Construction Contract)		\$1,698,228
	8.	Moveable Equipment (List all equipment over \$50,000)		\$486,134 (no items over \$50,000)
	9.	Other (Specify)		
В.:	Acq	uisition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)		
	2.	Building only		
	3.	Land only		
	4.	Equipment (Specify)		
	5.	Other (Specify)		
C.	Fina	incing Costs and Fees:		
	1.	Interim Financing		
	2.	Underwriting Costs		
	3.	Reserve for One Year's Debt Service		
	4.	Other (Specify)		
D.		Estimated Project Cost (A+B+C)		\$2,881,362
E.	COI	CON Filing Fee		\$6,034
F.	Tota (D+l	al Estimated Project Cost		
	(U+1		DTAL	\$2,887,396

September 25, 2014 4:05pm

Attachment 9

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available **Septembery25**, 2014 agency. The fiscal year begins in <u>January</u> (Month). 4:05pm

agency. The listal year begins in <u>January</u> (Month).			(<u>, † /</u>		
			Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
A.	Utiliz	ation Data (Adjusted Admissions)	14,330	15,146	15,967
B.	Reve	enue from Services to Patients			
	1.	Inpatient Services	\$147,022,000	\$178,940,000	\$222,998,000
	2.	Outpatient Services	162,648,000	196,626,000	221,909,000
	3.	Emergency Services	34,577,000	_41,567,000	52,971,000
	4.	Other Operating Revenue	2,312,000	2,145,000	1,055,000
		(Specify)			
		Gross Operating Revenue	\$ <u>346,559,000</u>	\$ <u>419,278,000</u>	\$ <u>498,923,000</u>
C.	Ded	uctions from Gross Operating Revenue			
	1.	Contractual Adjustments	\$221,391,000		\$351,127,000
	2. 🖟	Provision for Charity Care	8,248,000	<u>8,372,000</u>	9,247,000
	3.	Provisions for Bad Debt	14,402,000	<u> 18,846,000</u>	24,538,000
		Total Deductions	\$ <u>244,041,000</u>	\$ <u>313,868,000</u>	\$ <u>384,912,000</u>
NET	OPE	RATING REVENUE	\$ <u>102,518,000</u>	\$ <u>105,410,000</u>	\$ <u>114,011,000</u>
D.	Ope	rating Expenses			
	1.	Salaries and Wages	\$ <u>45,972,000</u>	\$ <u>45,996,000</u>	\$ <u>48,697,000</u>
	2.	Physician's Salaries and Wages	·		
	3.	Supplies	<u>16,054,000</u>	16,662,000	<u>17,116,000</u>
	4.	Taxes	6,945,000	6,959,000	10,112,000
	5.	Depreciation	9,397,000	9,640,000	8,408,000
	6.	Rent	507,000	171,000	618,000
	7.	Interest, other than Capital			<u> </u>
	8.	Management Fees:			
		a. Fees to Affiliates	3,741,000	4,090,000	4,408,000
		b. Fees to Non-Affiliates	-		3 01
	9.	Other Expenses – Specify on Page 21	14,961,000	<u> 17,589,000</u>	18,246,000
		Total Operating Expenses	\$ <u>97,577,000</u>	\$ <u>101,106,000</u>	\$ <u>107,605,000</u>
E.	Othe	er Revenue (Expenses) – Net (Specify)	\$	\$	\$
NET	OPE	RATING INCOME (LOSS)	\$ <u>4,941,000</u>	\$ <u>4,304,000</u>	\$ <u>6,406,000</u>
F.	Capi	ital Expenditures			
	1.	Retirement of Principal	\$	\$	\$
	2.	Interest			
135		Total Capital Expenditures	\$	\$	\$
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			\$ <u>4,941,000</u>	\$ <u>4,304,000</u>	\$ <u>6,406,000</u>

HISTORAL DATA CHART - OTHER EXPENSES

September 25, 2014 4:05pm

		7.0
Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
\$_2,564,000	\$2,597,000	\$ 3,472,000
4,833,000	5,323,000	5,291,000
3,485,000	3,485,000	3,854,000
2,583,000	2,584,000	2,665,000
(181,000)	843,000	604,000
(89,000)		(a
1,766,000	2,757,000	2,360,000
\$ <u>14,961,000</u>	\$ <u>17,589,000</u>	\$ <u>18,246,000</u>
	\$2,564,000 4,833,000 3,485,000 2,583,000 (181,000) (89,000) 1,766,000	\$\ \begin{array}{cccccccccccccccccccccccccccccccccccc

PROJECTED DATA CHART - OTHER EXPENSES

OTHER EXPENSES CATEGORIES	Year <u>2017</u>	Year <u>2018</u>
1. Professional Fees	\$	\$
2. Contract Services		·——
3. Repairs and Maintenance		59,000
4. Utilities	12,000	12,000
5. Marketing, recruiting, etc.	30,00	30,000
6.		
7.		
Total Other Expenses	\$42,000	\$ 101,000

September 25, 2014 4:05pm

Attachment 10

September 25, 2014 (x3) DATE SURVEY COMPLETED 4:05pm

STATEMENT OF DEFICIENCIES	
AND PLAN OF CORRECTION	

Division of Health Care Facilities (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION A, BUILDING: 01 - MAIN BUILDING

TNP531116

B. WING

06/26/2008

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

555 HARTSVILLE PIKE GALLATIN, TN 37066

SUMNER REGIONAL MEDICAL CENTER

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 871	1200-8-108 (1) Building Standards (1) The hospital must be constructed, arranged, and maintained to ensure the safety of the patient.	H 871		
	This Rule is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to comply with the life safety codes.			
	The findings included: On 6/25/08 at approximately 3:00 PM< inspection of the 3rd floor physical therapy handicapped bathroom, the handicapped whirl pool treatment room and the handicapped admitting bathroom revealed no strobe lights. ADA I			
	Inspection of the 4th floor clean storage room north revealed a stained ceiling tile TDOH 1200-8-108			
	On 6/26/08 at approximately 8:00 AM, inspection of the handicapped bathroom in the admitting area revealed a broken ceiling tile. TDOH 120-8-108			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/08

0EGD21



September 25, 2014 4:05pm

State Form: Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number TNP531116	(Y2) Multiple Construction A. Building 01 - MAIN BUILDING B. Wing		(Y3) Date of Revisit 9/4/2008	
Name of Facility		Street Address, City, State, Zip Code		
SUMNER REGIONAL MEDICAL CENTER		555 HARTSVILLE PIKE		
SOWNER REGIONAL MEDICAL CENTER		GALLATIN, TN 37066		

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully Identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) I	tem		(Y5)	Date	(Y4) Item	(Y5)	Date	(Y4) Item	(Y5)		ate
		H0871 1200-8-108 (1)	Correction Completed 08/10/2008	Reg. #			Reg. #			Correction Completed
	Prefix Reg. # LSC				ID Prefix Reg. # LSC			Reg. #			Correction Completed
	Prefix Reg. # LSC			Correction Completed	ID Prefix Reg. # LSC		Correction Completed	Reg. #			Correction Completed
	Prefix Reg. # LSC			Correction Completed	Reg. #			Reg. #			Correction Completed
	Prefix Reg. # LSC					-					
Review State A		3.1	Reviewed I	Ву	Date:	Signature of Surv	eyor:	<u> </u>	Da	ite:	
Review CMS R	ved By		Reviewed I	Ву	Date:	Signature of Surve	eyor:		Da	ate:	
Follow	vup to	Survey Comple 6/26/			: 			Deficiencies. Was (CMS-2567) Sent	4 - 45 - F 1114 - O	'ES	NO

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA

IDENTIFICATION NUMBER:

440003

(X3) DATE SURVEY 4:0 COMPLETED

B. WING

06/26/2008

NAME OF PROVIDER OR SUPPLIER

STATEMENT OF DEFICIENCIES

AND PLAN OF CORRECTION

STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE

(X2) MULTIPLE CONSTRUCTION

A. BUILDING 01 - MAIN BUILDING

SUMNER	REGIONAL MEDICAL CENTER		GALLATIN, TN 37066			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE		
K 025	NFPA 101 LIFE SAFETY CODE STANDARD	КО	25			
	Smoke barriers are constructed to provide at least a one half hour fire resistance rating in accordance with 8.3. Smoke barriers may terminate at an atrium wall. Windows are protected by fire-rated glazing or by wired glass panels and steel frames. A minimum of two separate compartments are provided on each floor. Dampers are not required in duct penetrations of smoke barriers in fully ducted heating, ventilating, and air conditioning systems. 19.3.7.3, 19.3.7.5, 19.1.6.3, 19.1.6.4					
	This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the smoke doors.	8				
	The findings included:					
	On 6/25/08 at approximately 12:00 Pm, inspection of the area above the smoke doors by room 429 revealed a penetration around a 1-inch conduit (2/5/8 inch dry wall). NFPA 101, 8.2.4.4.1					
	Inspection of the corridor wall above the ceiling by the 2nd floor sleep room revealed an i-inch hole in the wall (2 5/8 inch dry wall). NFPA 101, 8.2.4.4.2					
K 029	NFPA 101 LIFE SAFETY CODE STANDARD	K0	29			
	One hour fire rated construction (with % hour fire-rated doors) or an approved automatic fire extinguishing system in accordance with 8.4.1 and/or 19.3.5.4 protects hazardous areas. When					
00 tT001	DIRECTORIS OF PROVIDER/SLIPPLIED DEPRESENTATIVE'S SIGNATURE		TITI F	(X6) DATE		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/2008

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

(X3) DATE SURVEY

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES COMPLETED **IDENTIFICATION NUMBER:** AND PLAN OF CORRECTION A. BUILDING 01 - MAIN BUILDING 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) K 029 Continued From page 1 K 029 the approved automatic fire extinguishing system option is used, the areas are separated from other spaces by smoke resisting partitions and doors. Doors are self-closing and non-rated or field-applied protective plates that do not exceed 48 inches from the bottom of the door are permitted. 19.3.2.1 This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the hazardous areas. The findings included: On 6/26/08 at approximately 9:00 AM, inspection of the 2nd floor electrical room revealed a 8 inch hole in the wall (2 5/8 inch dry wall). NFPA 101, 19.3.2.1 K 052 NFPA 101 LIFE SAFETY CODE STANDARD K 052 A fire alarm system required for life safety is installed, tested, and maintained in accordance with NFPA 70 National Electrical Code and NFPA 72. The system has an approved maintenance and testing program complying with applicable requirements of NFPA 70 and 72. 9.6.1.4

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES

(X3) DATE SURVEY 4:05 pm

AND PLAN OF CORRECTION		IDENTIFICATION NUMBER:	A. BUILD	ING	01 - MAIN BUILDING	00,000		•
		440003	B. WING		(06/2	26/2008	
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER				1	STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			IX F	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)	BE	(X5) COMPLETION DATE	
K 052	Continued From page	2	К	052	2			
	Based on observatio	not met as evidenced by: n and inspection, it was y failed to maintain the alarm						
	The findings included	:						
	of the facility revealed	imately 1:00 PM, inspection d pull stations were mounted e on 1st, 2nd, 3rd, and the PA 72, 2-8-1						
	recover area, and the revealed the pull stati equipment. NFPA 72,							
K 054	All required smoke de activating door hold-c	etectors, including those open devices, are approved, and tested in accordance r's specifications. 9.6.1.3	K	054	1			
	Based on observatio	not met as evidenced by: n and inspection, it was y failed to maintain the						
	The findings included	:						
	of the facility revealed	imately 2:00 PM, inspection d smoke detectors were too ers and the air return vents the basement floors. NFPA						

(X2) MULTIPLE CONSTRUCTION

DEPARTI	MENT OF HEALTH AN	ID HUMAN SERVICES				RM APPROVED
CENTER	S FOR MEDICARE &	MEDICAID SERVICES			Seyfe	19 19 19 19 19 19 19 19 19 19 19 19 19 1
	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	IPLE CONSTRUCTION IG 01 - MAIN BUILDING	(X3) DA	TE SURVEY 4:05pm
		440003	B. WING_		0	06/26/2008
NAME OF P	ROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE	***	
SUMNER	REGIONAL MEDICAL CE	ENTER		555 HARTSVILLE PIKE GALLATIN, TN 37066		
		WENT OF DESIGNATION		PROVIDER'S PLAN OF CORI	PECTION	(X5)
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG		SHOULD BE	COMPLETION DATE
K 062	NFPA 101 LIFE SAFE	ETY CODE STANDARD	ко	062		
	condition and are insp	ned in reliable operating				
	Based on observatio	not met as evidenced by: on and inspection, it was y failed to maintain the				
	The findings included	l:				
	of the 2nd floor nurse	rimately 1:00 PM, inspection ery area and in the morgue heon plates were missing.				
K 064	sprinkler heads were	hen area revealed the corroded. NFPA 13, 3.2.6.1 ETY CODE STANDARD	К	064		
		shers are provided in all cies in accordance with NFPA 10				
		not met as evidenced by: on and inspection, it was				

extinguishers.

The findings included:

detrermined the facility failed to maintain the fire

FORM APPROVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

September 25912014
(X3) DATE SURVEY 4:05 pm

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING		(X3) DATE COMPI	SURVEY 4:05	
		440003	B. WING	-		06/2	26/2008
	ROVIDER OR SUPPLIER	ENTER	•	5	STREET ADDRESS, CITY, STATE, ZIP CODE 155 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)	BE	(X5) COMPLETION DATE
K 064	Continued From page		К	064			
	inspection of the corr break room 3 north, a	idors by rooms 404, 405, and the 1st floor wound care tinguishers were not checked					
	revealed the fire extir equipment. NFPA 10	e basement wood shop nguishers were blocked with , 1.6.3			ds.		
K 067	Heating, ventilating, a with the provisions of in accordance with the	ETY CODE STANDARD and air conditioning comply f section 9.2 and are installed ne manufacturer's 5.2.1, 9.2, NFPA 90A,	K	067			
	Based on observation	not met as evidenced by: on and inspection, it was y failed to maintain the					
	The findings included	1:					
	of 2 north and 2 west	kimately 1:45 PM, inspection t soiled utility rooms revealed te not working. NFPA 101,					
K 141	revealed the exhaust NFPA 101, 19.5.2.1	ement elevator room t fan vent cover was dirty ETY CODE STANDARD	K	141			

CODM ADDDOVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sewenness38203912 CENTERS FOR MEDICARE & MEDICAID SERVICES (X3) DATE SURVEY 4:05 (X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING 01 - MAIN BUILDING B. WING 440003 06/26/2008 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) K 141 K 141 Continued From page 5 Non-smoking and no smoking signs in areas where oxygen is used or stored are in accordance with 19.3.2.4, NFPA 99, 8.6.4.2. This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the no smoking signs. The findings included: On 6/25/08 at approximately 12:30 PM, inspection of the 3rd floor physical therapy storage room and room 303 revealed cylinders of oxygen being stored and no precautionary signs posted. NFPA 99, 8.6.4.2 K 147 NFPA 101 LIFE SAFETY CODE STANDARD K 147 Electrical wiring and equipment is in accordance with NFPA 70, National Electrical Code. 9.1.2 This STANDARD is not met as evidenced by: Based on observation and inspection, it was detrermined the facility failed to maintain the electrical system. The findings included: On 6/25/08 at approximately 1:15 PM, inspection

of the 3rd floor rehab therapy office and the 2nd floor laxation room revealed electrical outlets next to the sinks were not ground fault circuit interrupters (GFCI). NFPA 70, 210-8-(a)(5)

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

	DF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING			SURVEY 4:05
		440003	B. WING			06/:	26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER				55	REET ADDRESS, CITY, STATE, ZIP CODE 15 HARTSVILLE PIKE ALLATIN, TN 37066		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPR DEFICIENCY)	BE	(X5) COMPLETION DATE
K 147	of the 1st floor nurses area, the lab, and in the electrical panels were NFPA 70, 110-26(a). Inspection of the 1st revealed the emergenot labelled with the electrical strength of the kitch laundry area revealed.	imately 6:30 AM, inspection s' administers' office, the er the EDS area revealed e blocked with equipment. floor emergency rooms ncy electrical outlets were electrical panels. NFPA 70, then area and the basement d not all of the electrical fault circuit interrupters	К	1147			

Department of Health and Human Services Centers for Medicare & Medicaid Services

SUPPLEMENTAL- 1

OMB NO. 0938-0390

Post-Certification Revisit Report

September 25, 2014

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the under, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

4:05pm

(Y1) Provider / Supplier / CLIA / Identification Number 440003	(Y2) Multiple Construction A. Building B. Wing	N BUILDING	(Y3) Date of Revisit 9/4/2008
Name of Facility		Street Address, City, State, Zip Code	
SUMNER REGIONAL MEDICAL CENTER		555 HARTSVILLE PIKE	
SOMMEN NEGIGIAL MEDIONE GENTEN		GALLATIN, TN 37066	

This report is completed by a qualified State surveyor for the Medicare, Medicald and/ or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the Identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

Y4) Item		(Y5)	Date	(Y4)	Item		(Y5)	Date	(Y4)	Item		(Y5)	Date
ID Prefix			Correction Completed 06/26/2008		ID Prefix			Correction Completed 07/18/2008					Correction Completed 07/15/2008
_	NFPA 101		2		_	NFPA 101				-	NFPA 101		=
LSC	K0025			_	LSC	K0029			(1)	LSC	K0052		
_	NFPA 101 K0054		Correction Completed 08/10/2008		Reg. #	NFPA 101 K0062		Correction Completed 08/10/2008		•	NFPA 101 K0064		Correction Completed 07/14/2008
-	NFPA 101 K0067		Correction Completed 08/10/2008		Reg.#	NFPA 101 K0141		Correction Completed 08/10/2008		Reg.#	NFPA 101 K0147		Correction Completed 08/10/2008
			Correction Completed		-			Correction Completed		Reg.#			Correction Completed
ID Prefix Reg. # LSC					ID Prefix Reg. # LSC			Correction Completed		ID Prefix Reg. # LSC			Correction Completed
Reviewed By		Reviewed	Ву	D	ate:	Signature o	of Surve	eyor:				Date:	
Reviewed By		Reviewed	Ву	D	ate:	Signature o	of Surve	eyor:				Date:	
Followup to	Survey Compl 6/26	leted on: /2008		-		Une	correcte				a Summary of to the Facility?	YES	NO
Form CMS -	2567R (0.02)					Page 1 of 1					Event ID:	0EGD22	

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUPPLEMENTAL - 1

FORM APPROVED

CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING B. WING 440003 06/26/2008 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) A 385 482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on observation, policy review and interview it was determined the hospital's nursing services failed ensure patient safety by not adhering to approved policies and procedures concerning 1 of 1 Malignant Hyperthermia carts. The findings included: The hospital failed to ensure an effective method for the storage and administration of medications used to treat Malignant Hyperthermia in accordance with the approved medical staff policies and procedures for 1 of 1 Malignant Hyperthermia carts. (REFER TO A 405) A 405 482.23(c)(1) ADMINISTRATION OF DRUGS A 405 All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/2008

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

Event ID: 0FGD11

procedures.

FORM ADDROVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

(3) DATE SURVEY 4:0 (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING _ 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PRFFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 405 Continued From page 1 A 405 This STANDARD is not met as evidenced by: Based on policy review, observation, and interview, it was determined the hospital failed to ensure an effective method for the storage and administration of medications used to treat Malignant Hyperthermia in accordance with approved medical staff policies and procedures for 1 of 1 Malignant Hyperthermia carts. The findings included: Review of the facility's "Malignant Hyperthermia Protocol" policy with a review date of May 2008 revealed the following documentation: "O.R. [Operating Room] will have supplies available to manage malignant hyperthermia...Malignant hyperthermia is a potentially fatal syndrome that can affect patients of any race and gender, particularly the young. It can occor in the O.R. and/or later in the PACU, as well as, any time in the immediate post-operative course...SUPPLIES: Immediately available on malignant hyperthermia emergency cart:...Dantrolene (36 amps)." Review of the facility's "Malignant Hyperthermia Cart" policy revised May 2008 revealed the following documentation: "1. The malignant hyperthermia cart will be checked by the R.N. [Registered Nurse] in surgery once a month to make sure all necessary medications and supplies...are present and in date...Medicine drawer checked daily Monday through Friday on regular workdays and on weekends and holidays

PRINTED: 09/23/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

Semena 15878 259 12014

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) D	ATE SURVEY 4:05		
		440003	B. WING			10	06/26/2008	
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER				555 H	ET ADDRESS, CITY, STATE, ZIP CODE IARTSVILLE PIKE LATIN, TN 37066			
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI- CROSS-REFERENCED TO THE AP DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE	
A 405	if OR is called in3. hyperthermia protocolocated on top of the and administration of are kept in the drawe pertain toThe maliglocated in the O.R. hat all times." Observation on 6-25 Room at 10:50 AM re Hyperthermia Cart of Dantrolene (a medicing Hyperthermia/a bioconsection of the pertain triggered general anesthetics. crisis include a rise in metabolism, muscle exceed 110 degrees cardiovascular collar bleeding or failure of a potentially fatal syninterview at 10:55 AN Services revealed the were ever on the car revealed no instruction use the Dantrolene. During an interview of Director of Pharmacy Dantrolene were in to Observation at 3:00 there were no vials of finding was confirmed Clinical Services. On 6/25/08 at 3:15 Fithe Cardiac Care University of the		A	405				

DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF DEFICIENCIES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA

_S	DMENUR838	06912	014
.5	(X3) DATE SURVEY COMPLETED		pm

AND PLAN OF	CORRECTION	IDENTIFICATION NUMBER:	A, BUILDING		J JOHN ELYES
		440003	B. WING		06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066	
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPR DEFICIENCY)	BE COMPLETION
A 457	On 6/25/08 at 3:25 PI Services stated to the President of Clinical Svials were in the Labo (L&D). The Director in the PACU but I for Observation in the L8 were 6 vials of Dantro (medication cart). Note the Dantrolene were observation. Interview Women's Center on 6 confirmed that there of the medication in the further stated when a were "I guess we womanual." 482.24(c)(1)(iii) VERI AUTHENTICATED B. All verbal orders must upon Federal and Stallaw that designates a authentication of vertical states.	e President of Clinical revation and interview. If the Director of Pharmacy is surveyor and the Vice Services that the other 6 or and Delivery Department further stated "it used to be got it is now in the L&D." (D at 3:40 PM revealed there olene in the L&D Pixes of instructions for the use of found at the time of we with the Director of the S-26-08 at 10:00 AM were no instructions on use the cart, and the Director sked where the instructions uld look in the policy BAL ORDERS ASED ON LAW It be authenticated based ate law. If there is no State is specific timeframe for the pal orders, verbal orders d within 48 hours.	A 45		
	Based on policy revi determined the facilit orders from physician	not met as evidenced by: ew and record review it was y failed to ensure verbal ns were signed by those y manner for three patients			

(X2) MULTIPLE CONSTRUCTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION 3) DATE SURVEY STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING_ 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL **PREFIX PREFIX** CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 457 A 457 Continued From page 4 (#31, #34, #39) of 40 patient records sampled. The findings include: Review of the facility's "Physician's Order: Verbal/Phone/Copied" policy revised February 2005 revealed the policy did not designate a time frame for physician signature. Medical record review revealed Patient #31 revealed the patient was admitted to the facility on 06/12/08. On 06/12/08 a verbal order was written at 2140 for "Ambien 10 milligrams, one dose now." A later untimed verbal order on 06/12/08 was written for "Normal saline flush each shift and as needed." These orders were not signed by the ordering physician as of the survey date of 06/26/08. Medical record review for Patient #34 revealed the patient was admitted to the facility on 06/11/08. On 06/11/08 the Anesthesia Preoperative Standing Orders were signed by the CRNA [Certified Registered Nurse Anesthetist] but were not signed as of the survey date of 06/26/08 by the attending physician. This included medication orders for "Versed 2 mg [milligrams] IV [intravenously]; Robinul 0.1 mg IV; Pepcid 20 mg IVPB[intravenously per bag]; Reglan 10 mg IV." Medical record review for Patient #39 revealed the patient was admitted to the facility on 06/09/08. On 06/09 08 the Physician Standing Order - OR form was signed by the Registered Nurse but there was no physician's signature on

the orders as of the survey date of 06/26/08. The orders included "IV 1000 ml normal saline with 50,000 units Bacitracin; Thrombin 20,000 units."

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X3) DATE SURVEY 4:0 (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETION DATE (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) 482.24(c)(2)(v) CONTENT OF RECORD -A 466 A 466 INFORMED CONSENT [All records must document the following, as appropriate:] Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent. This STANDARD is not met as evidenced by: Based on policy review and review of medical records it was determined the facility failed to adhere to its policy by not obtaining an informed consent for one patient (#5) of 40 patient's sampled. The findings include: Review of the facility's "Consents for Treatment" policy revised June 2008 revealed the following documentation: "A consent for medical treatment is obtained for each patient treated in the hospital... TYPES OF CONSENTS: 1. General consent for treatment - signed on each admission and wittnessed...In the event that consent cannot be obtained from the adult patient and there is no legal guardian the following is a list of who may give consent in order of priority: 2. Adult children..." Medical record review revealed Patient #5 was admitted to the Emergency Department on 04/20/08 at 0948 with complaints of rash with

itching all over and nausea. The patient had blood drawn, received an EKG[electrocardiogram] and CT [computerized tomography] while in the

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

MD NO -0039-0801-

,	(X3) DATE SURVEY COMPLETED	4:05pm
		1

06/26/2008

(X5) COMPLETION DATE

(X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X2) MULTIPLE CONSTRUCTION IDENTIFICATION NUMBER: A. BUILDING

440003

B. WING

PREFIX

TAG

STREET ADDRESS, CITY, STATE, ZIP CODE

PROVIDER'S PLAN OF CORRECTION

(EACH CORRECTIVE ACTION SHOULD BE

CROSS-REFERENCED TO THE APPROPRIATE

DEFICIENCY)

555 HARTSVILLE PIKE GALLATIN, TN 37066

SUMNER REGIONAL MEDICAL CENTER

NAME OF PROVIDER OR SUPPLIER

(X4) ID

PREFIX

TAG

A 466 | Continued From page 6 Emergency Department. The patient was accompanied by a daughter. The "Authorization for Treatment and Assignment of Benefits" form was not signed by the patient or the daughter. On the form it is documented "Pt.[patient] discharged before signing." The patient's signature was on the "Discharge Instructions". The patient was discharged at 1310. 482.25 PHARMACEUTICAL SERVICES A 490

SUMMARY STATEMENT OF DEFICIENCIES

(EACH DEFICIENCY MUST BE PRECEDED BY FULL

REGULATORY OR LSC IDENTIFYING INFORMATION)

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

This CONDITION is not met as evidenced by: Based on policy review, observation and interview it was determined the hospital's pharmaceutical services failed to meet the needs of the patients by not following developed policies and procedures for availability and instructions for use for medication to treat Malignant Hyperthermia and by not ensuring unusable medications were not available for use by facility staff.

A	466	ľ
		М

A 490

Event ID: 0EGD11

Facility ID: TNP531116

If continuation sheet Page 7 of 15

EODM ADDDOVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

SOMPOND 1838 25912014

	OF DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			ONSTRUCTION	(X3) DATE COMP	SURVEY 4:05
		440003	B. WING			06/2	26/2008
	ROVIDER OR SUPPLIER	ENTER	•	555	REET ADDRESS, CITY, STATE, ZIP CODE HARTSVILLE PIKE ILLATIN, TN 37066		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF CORRECTIC (EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROP DEFICIENCY)) BE	(X5) COMPLETION DATE
A 492	interview, it was deter pharmacist failed to end facility policy and produced the second facility policy and produced the second facility policy and produced facility policy and produced facility policy and produced facility fail drug from usable sto 482.25(a)(1) PHARM A full-time, part-time, must be responsible	d: eview, observation, and rmined the hospital ensure adequate supervision use procedures according to redure for 1 of 1 Malignant		490			
	Based on policy rev interview, it was dete pharmacist failed to of drug storage and facility policy and pro Hyperthermia carts. The findings included Review of the facility	ensure adequate supervision use procedures according to ocedure for 1 of 1 Malignant					

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

S	emenungs8	2912014
100	(X3) DATE SURVEY COMPLETED	4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	, ,	IPLE CONSTRUCTION NG	(X3) D.	(X3) DATE SURVEY 4:05		
		440003	B. WING_			06/26/2008		
	ROVIDER OR SUPPLIER	ENTER		STREET ADDRESS, CITY, STATE, ZIP OF S55 HARTSVILLE PIKE GALLATIN, TN 37066	CODE			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI) TAG	PROVIDER'S PLAN OF ((EACH CORRECTIVE ACT CROSS-REFERENCED TO DEFICIENCE	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE		
A 492	[Operating Room] will manage malignant by hyperthermia is a pot can affect patients of particularly the young and/or later in the PA the immediate post-courseSUPPLIES: malignant hyperthermic art:Dantrolene (36 Review of the facility Cart" policy revised following documentar hyperthermia cart wil [Registered Nurse] ir make sure all necess suppliesare presend drawer checked daily regular workdays and of OR is called in3. hyperthermia protocolocated on top of the and administration of are kept in the drawer pertain toThe maligilocated in the O.R. hat all times." Observation on 6-25 Room at 10:50 AM rehyperthermia Cart con Dantrolene (a medical Hyperthermia/a biocoresponse "triggered general anesthetics. crisis include a rise in	g documentation: "O.R. Il have supplies available to yperthermiaMalignant tentially fatal syndrome that any race and gender, g. It can occor in the O.R. aCU, as well as, any time in yperative Immediately available on nia emergency amps)." It s "Malignant Hyperthermia May 2008 revealed the tion: "1. The malignant I be checked by the R.N. in surgery once a month to	A	492				

PRINTED: 09/23/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION X3) DATE SURVEY STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING B. WING 06/26/2008 440003 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 492 Continued From page 9 A 492 exceed 110 degrees F. Complication include: cardiovascular collapse, brain damage, internal bleeding or failure of other body systems. This is a potentially fatal syndrome.). During an interview at 10:55 AM the Director of Surgical Services revealed that the 30 vials were all that were ever on the cart. Further observation revealed no instructions were available on how to use the Dantrolene. During an interview on 6-25-08 at 2:50 PM the Director of Pharmacy Services alleged 6 vials of Dantrolene were in the Recovery Room (PACU). Observation at 3:00 PM in the PACU revealed there were no vials of Dantrolene present. This finding was confirmed by the Vice President of Clinical Services. On 6/25/08 at 3:15 PM, interview with 2 nurses in the Cardiac Care Unit revealed no Dantrolene was kept in that department. This was also confirmed by the Vice President of Clinical Services during observation and interview. On 6/25/08 at 3:25 PM the Director of Pharmacy Services stated to the surveyor and the Vice President of Clinical Services that the other 6 vials were in the Labor and Delivery Department (L&D). The Director further stated "it used to be in the PACU but I forgot it is now in the L&D." Observation in the L&D at 3:40 PM revealed there were 6 vials of Dantrolene in the L&D Pixes (medication cart). No instructions for the use of the Dantrolene were found at the time of observation. Interview with the Director of the Women's Center on 6-26-08 at 10:00 AM

confirmed that there were no instructions on use of the medication in the cart, and the Director further stated when asked where the instructions

(INTED: 09/23/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A, BUILDING B. WING 06/26/2008 440003 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER **GALLATIN, TN 37066** PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL **PREFIX** PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) Continued From page 10 A 492 A 492 were "I guess we would look in the policy manual." 482.25(b)(3) UNUSABLE DRUGS NOT USED A 505 A 505 Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, it was determined the facility failed to remove one expired drug from usable stock. The findings included: Observation during a tour of the facility off-site rehabilitation clinic at the "Maple Street Location" revealed one 5 milliliter (ml) vial (Lot #201791) of Dexamethasone Sodium Phosphate 4 milligrams (mg) per ml with an expiration date of April 2008. The findings were confirmed in an interview with the scheduler (only staff member on-site at time of tour) on 6/24/08 at 1:10 PM. Review of the facility policy entitled, "Out-Dated Drugs (Storage and Disposition)" dated February 2006 revealed the following: "The Pharmacy stock and all drug storage areas are checked monthly for out-dated drugs." "Some drugs are destroyed in the hospital by either being poured down the sink or shipped out according to the hospital's waste disposal procedure."

Organization

482.28(a) ORGANIZATION

A 619

A 619

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

(X3) DATE SURVEY 4:0 (X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING B, WING 440003 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE **555 HARTSVILLE PIKE** SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 619 A 619 Continued From page 11 This STANDARD is not met as evidenced by: Based on observation and interview, it was determined the hospital dietary manager failed to provide responsible daily management to ensure a clean and sanitary dietary environment. The findings included: 1. Observation of the hospital kitchen on 6-25-08 at 8:30 AM to 9:45 AM revealed the following: a. Refrigerator #2 revealed no thermometer was available for observation of the temperature of the b. There was no lid on the receiving container of the tea brewer. c. The Hobart mixer had debris on the rim above the bowl. d. The Tomato slicer, identified as clean by the Director of Nutritional Service, had red matter noted in the blades. e. Refrigerator #5 had debris noted on the bottom shelf. f. Refrigerator #6 had a tray on the shelf inside with debris noted. g. The hot line counter had debris noted on the bottom shelf. h. There were 60, 4 ounce cereal bowls, identified as clean by Dietary Aide I, with dried food particles inside and outside of the bowls. i. There were 10 fans above the food preparation counters (5 on each side) with large amounts of

debris blowing out of them.

CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER **GALLATIN. TN 37066** PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PRFFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 619 Continued From page 12 A 619 j. A Southbend 6 burner stove was observed with large amounts of grease/debris stuck to all parts of the stove. k. Oven #1 and #2 had large amounts of grease/debris noted on the knobs, inside and front of ovens. The grease trap located in front of the stove and ovens was noted to be full with large pieces of food in the trap also. Observation of the dry food storage area revealed the following: I. A 9.7 ounze bag of Splenda with brown, sticky debris on the outside of the package. m. A plastic canister of Honey Cajun mix with a lid that was not covering the container. 3. The tops of raisin/chocolate covered nuts container, and container of walnuts with sticky matter on the ntops with debris stuck to them. o. A 1 gallon plastic bottle of browning seasoning sauce without a lid with plastic wrap covering it. The plastic wrap with a hole in opening. p. A 1 gallon container of hickory seasoning/soy sauce with brown liquid on the outside of the g. Multiple cans of beets (6 pounds), black bean (6 pounds, 4 ounces), sliced green olives (3 pounds 7 ounces), instant chocolate/strawberry mouse cans with a thick coat of dust on the lids. r. Large plastic bins of hard boiled, peeled eggs, and cranberry nut batter with pieces of brown matter on the lids. s. A 20 pound box of frozen beans in the walk in freezer not covered. All observations were confirmed by the Administrator and the Director of Nutritional Services.

2. During a tour of the dietary department on

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

SUPPLEMENTAL- 1

PRINTED: 09/23/2014

Sement Server 4:05pm

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY 4:05		
		440003	B. WING			06/	26/2008	
	ROVIDER OR SUPPLIER	ENTER		555	REET ADDRESS, CITY, STATE, ZIP CODE HARTSVILLE PIKE LLATIN, TN 37066			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE	
A 619	water which caused a employees. This finding was conf Nutrition Services on 482.41(c)(2) FACILIT EQUIPMENT MAINT Facilities, supplies, al	ved the floor in the as 3/4 covered with standing a safety hazard for irmed with the Director of 06/25/08. IES, SUPPLIES,		724				
	Based on observation determined the facility premises, supplies are sanitary manner which quality for staff and puring a tour of the dimensional o	ietary department on rved the floor in the as 3/4 covered with standing a safety hazard for irmed with the Director of						

PRINTED: 09/23/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION 3) DATE SURVEY COMPLETED IDENTIFICATION NUMBER: AND PLAN OF CORRECTION A. BUILDING_ 440003 B. WING 06/26/2008 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 (X5) COMPLETION DATE PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES ID (X4) ID (EACH CORRECTIVE ACTION SHOULD BE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 724 Continued From page 14 A 724 During a tour of the PACU [Post Anesthesia Recovery Room] on 06/25/08 it was observed the monitor tops, handwashing gel containers, and stands were covered with a thick layer of dust in five bays in the department. This finding was confirmed with the Director of Surgical Services on 06/25/08. During a tour of the Surgical Services Department on 06/25/08 it was observed the floor in Endoscopy Room #2 was sticky. This finding was confirmed with the Director of Surgical Services on 06/25/08. Observation on 6/24/08 at 4:45 PM during a tour of the off-site rehabilitation clinic at the "Sumner Crossroads, White House Location" revealed a Hydrocollator, a device used to heat wet hot packs, in the main treatment area that contained wet hot packs for heat therapy. Continued observation revealed no evidence of temperature logs to check the heat level of the water and heat packs. An interview with the physical therapist confirmed the finding and that the facility policy is to check the water temperature daily and document on a log. Observation on 6/24/08 at 4:55 PM revealed a freezer used to store ice packs for ice/cold therapy. Further review revealed no temperature logs to check the temperature of the device to ensure proper operation and temperature level. An interview with the physical therapist at the time of the observation confirmed the finding and that the facility policy is to check the freezer temperature daily and log the temperature.

Department of Health and Human Services Centers for Medicare & Medicaid Services

SUPPLEMENTAL- 1

OMB NO. 0938-0390

September 25, 2014

Post-Certification Revisit Report

4:05pm

Public reporting for this collection of Information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

	Provider / Supplier / CLIA / Identification Number 440003	(Y2) Multiple Construction A. Building B. Wing		(Y3) Date of Revisit 8/6/2008
Name o	of Facility	1.	Street Address, City, State, Zip Code	
SUMNER REGIONAL MEDICAL CENTER			555 HARTSVILLE PIKE GALLATIN, TN 37066	

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/ or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully Identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item		(Y5)	Date	(Y4)	Item		(Y5)	Date	(Y4)	Item	(Y5) [Date
ID Prefix Reg. # LSC	A0385 482.23		Correction Completed 07/31/2008		ID Prefix Reg. # LSC	A0405 482.23(c)(1)		Correction Completed 07/31/2008		ID Prefix Reg. # LSC	A0457 482.24(c)(1)(iii)		Correction Completed 07/31/2008
ID Prefix Reg. # LSC	A0466 482.24(c)(2)(v)		Correction Completed 07/31/2008		ID Prefix Reg. # LSC			Correction Completed 07/31/2008			A0492 482.25(a)(1)		Correction Completed 07/31/2008
ID Prefix Reg. # LSC	A0505 482.25(b)(3)		Correction Completed 07/31/2008		ID Prefix Reg. # LSC	A0619 482.28(a)		Correction Completed 07/31/2008		ID Prefix Reg. # LSC	482.41(c)(2)		Correction Completed 07/31/2008
ID Prefix Reg. # LSC			Correction Completed		ID Prefix Reg, # LSC					ID Prefix Reg. # LSC	(======================================		
ID Prefix Reg. # LSC					Reg.#					Reg. #			
Reviewed By	77	Reviewed I	Ву	Da	te:	Signature o	of Surve	eyor:				Date:	
Reviewed By		Reviewed I	Ву	Da	te:	Signature o	of Surve	eyor:				Date:	
Followup to	Survey Compl 6/26	-		Check Und	for any correcte	Uncorrected d Deficiencles	Defici (CM	encies. Was S-2567) Sent	a Summary of to the Facility?	YES	NO		

Division of Health Care Facilities tember 25 (X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: _ B. WING 06/26/2008 TNP531116 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE SUMNER REGIONAL MEDICAL CENTER GALLATIN, TN 37066 PROVIDER'S PLAN OF CORRECTION (X5) SUMMARY STATEMENT OF DEFICIENCIES (X4) ID COMPLETE (EACH CORRECTIVE ACTION SHOULD BE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PRÉFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) H 404 H 404 1200-8-1-.04 (4) Administration (4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement. This Rule is not met as evidenced by: Based on review of facility documents, observation, and interview it was determined the facility failed to follow its written policies for temperature monitoring and medications. The findings include: During a tour of the Labor and Delivery Department on 06/24/08 it was determined the temperature in the refrigerator which is designated for breast milk was 28 degrees F [Farenheit]. Review of the facility policy for this refrigerator revealed the temperature was to be in the range of 35 degrees to 40 degrees F. Review of the temperature log for this refrigerator revealed the temperature was consistently in the 20 - 30 degree range for the months of May and June, 2008. There was no documentation that any corrective action had been instituted. Interview with the Director of Women's Services on 06/24/08 at 2:30 PM in the Administrative Conference Room revealed a work order had not

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

been initiated to correct the temperature. The Director continued on that the staff had been turning up the temperature to the correct range. This was not documented on the temperature log.

TITLE

(X6) DATE

07/14/08

0EGD11

06/26/2008

Division of Health Care Facilities September 25 (X3) DATE SURVEY (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: _

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

B. WING

555 HARTSVILLE PIKE

TNP531116

SUMNER REGIONAL MEDICAL CENTER **GALLATIN. TN 37066** (X5) COMPLETE DATE SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX **PREFIX** REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) H 404 H 404 Continued From page 1 During a tour of the Surgical Services Department on 06/25/08 it was determined the temperature of the blanket warmer in the Operating Room was 151 degrees F and the temperature of the blanket warmer in the PACU[Post Anesthesia Recovery Room] was 134 degrees F. Review of the facility policy revealed the temperature of the blanket warmers is to be 120 degrees F. This finding was confirmed with the Director of Surgical Services on 06/25/08.

Division of Health Care Facilities

0EGD11



September 25, 2014 4:05pm

State Form: Revisit Report

lden	rider / Supplier / CLIA / tification Number 531116	(Y2) Multiple Construction A. Building B. Wing		(Y3) Date of Revisit 8/6/2008		
Name of Facility SUMNER REGIONAL MEDICAL CENTER			Street Address, City, State, Zlp Code			
			555 HARTSVILLE PIKE			
SOMME	IN NEGIONAL MEDIOAL GENTEN		GALLATIN, TN 37066			

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item		(Y5)	Date	(Y4) Item	(Y5)	Date	(Y4)	Item	(Y	5) [Date
ID Prefix	H0404		Correction Completed 07/31/2008	ID Prefix		Correction Completed		ID Prefix			Correction Completed
Reg. # LSC	1200-8-104 (4	l) 		Reg. # LSC		ir.		Reg. # LSC			=
ID Prefix Reg. # LSC			Correction Completed	ID Prefix Reg. # LSC		Correction Completed		ID Prefix Reg. # LSC			Correction Completed
ID Prefix Reg. # LSC			Correction Completed	ID Prefix Reg. # LSC		Correction Completed		ID Prefix Reg. # LSC			Correction Completed
ID Prefix Reg. # LSC			Correction Completed	ID Prefix Reg. # LSC		Correction Completed		ID Prefix Reg. # LSC			Correction Completed
ID Prefix Reg. # LSC			Correction Completed	ID Prefix Reg. # LSC				Dag #			Correction Completed
							120				
Reviewed By		Reviewed i	Зу	Date:	Signature of Surve	yor:	1			Date:	
Reviewed By		Reviewed I	Зу	Date:	Signature of Surve	yor:				Date:	
Followup to Survey Completed on: 6/26/2008			Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?						YES	NO	
STATE FORM: DEVISIT REPORT (5/00)			Page 1 of 1 Event ID:)· NE	GD12		

September 25, 2014 4:05pm

Attachment 11



PROJECT COMPLETION FORECAST CHART

September 25, 2014 4:05pm

Enter the Agency projected Initial Decision date, as published in T.C.A. §68-11-1609(c): Dec. 2014

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

		DAYS	Anticipated Date
Pha	se	REQUIRED	(MONTH/YEAR)
1.	Architectural and engineering contract signed		Dec. 2014
2.	Construction documents approved by the Tennessee Department of Health	90	April. 2015
3.	Construction contract signed	90	April 2015
4.	Building permit secured	120	May 2015
5.	Site preparation completed	N/A	N/A
6.	Building construction commenced	145	May 2015
7.	Construction 40% complete	210	July 2015
8.	Construction 80% complete	270	Sept. 2015
9.	Construction 100% complete (approved for occupancy)	330	Nov. 2015
10.	*Issuance of license	330	Nov. 2015
11.	*Initiation of service	345	Dec. 2015
12.	Final Architectural Certification of Payment	345	Dec. 2015
13.	Final Project Report Form (HF0055)	420	Feb. 2016

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

^{*} For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

ORIGINAL-SUPPLEMENTAL-2

Sumner Regional Medical Center CN1409-041

BUTLER | SNOW



September 29, 2014 11:40am

September 29, 2014

HAND DELIVERY

Jeff Grimm, Examiner Tennessee Health Services and Development Agency Andrew Jackson Building, 9th Floor 502 Deaderick Street Nashville, TN 37243

RE: Certificate of Need Application CN1409-041

Sumner Regional Medical Center -

Initiation of PET Service on Outpatient Campus of Hospital

Dear Mr. Grimm:

Responses to the questions in your letter dated September 29, 2014, are below. The required affidavit is enclosed at the end of this response. Please let us know if you need additional information.

1. Section B, Project Description, Item II.E. and Section C, Economic Feasibility, Item 1 (Project Cost Chart)

The revised quote extending the expiration date to 12/22/2014 and the revised Project Cost Chart for the addition of \$199,500 to the cost of the PET/CT unit for sales tax and freight are noted.

However, it appears that the Filing Fee in line E of the chart, should also have been revised as a result of the increase in the cost of the PET/CT unit. It appears that the new fee would amount to \$6,483, an increase of \$449. This change would also change the grand total in line F. Please remit the additional amount and provide a replacement page with the revised Project Cost Chart.

<u>Response</u>: A replacement page (20-R(2)) for the Project Cost Chart and a check in the amount of \$449 are enclosed.

Jeff Grimm September 29, 2014 Page 2

September 29, 2014 11:40am

Given the 160 miles distance from the cyclotron to the proposed PET/CT location at Sumner Station, what is the life of the material that is required to account for driving times under normal conditions?

<u>Response</u>: SRMC understands that FDG has a half-life of slightly less than 2 hours. Cardinal Health ships FDG daily to its nuclear pharmacy distribution site in Nashville, for subsequent distribution to PET sites in the region that it services. In addition to the cyclotron in Louisville, Cardinal Health has cyclotrons in Knoxville, Birmingham and Memphis that can be the source of FDG. Based on the fact that Cardinal is already servicing PET units in the region, SRMC is confident of Cardinal Health's ability to provide timely delivery of FDG with the requisite degree of radioactivity for PET patients at Sumner Station.

2. Section C, Need. Item 6

The clarification of the methodology used to determine the utilization of the proposed PET service by Sumner & Macon County residents is noted.

Is it correct that, given the higher projected capture rate in Year 3, that utilization, revenue, expenses and net operating income can remain as projected for Years 1 and 2 as identified in the Projected Data Chart? Please confirm.

<u>Response</u>: Yes, the utilization, revenue, expenses and net operating income in Years 1 and 2 are based in SRMC's conservative projections for those years.

3. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

<u>Historical Data Chart</u> - Thank you for the clarification and submission of the Revised Historical Data Chart.

In looking at same, it was noted that inpatient gross operating revenue increased by approximately 25% from \$178,940,000 in fiscal year 2012 to \$222,998,000 in FY2013. What accounts for this change when adjusted admissions only increased by approximately 4%during the period?

<u>Response</u>: The unit of measure used, Adjusted Admissions, factors in outpatient volume as well as inpatient volume. Inpatient volumes increased from 2012 to 2013 disproportionately to increases in outpatient volumes. The same trend has held true in 2014. Since inpatient admissions generate more gross revenue than outpatient admissions, the disproportionately larger increase in inpatient admissions caused inpatient gross revenue to grow by a larger percentage than percentage growth in adjusted admissions.

<u>Projected Data Chart</u> – What is the equivalent amount in procedures that ties to the projected charity cost of \$65,000 in Year 1 of the project (line C.3 of the chart)?

Jeff Grimm September 29, 2014 Page 3

SUPPLEMENTAL-2

September 29, 2014 11:40am

Response: The charity care cost of \$65,000 equates to 9 PET scans.

The \$115 per dose cost associated with the FDG/radioactive material and the 160 mile distance from the vendor's cyclotron in Louisville, Ky. is noted. What are the annual amounts for same that are included in the supply costs of the Projected Data Chart (line D.3)?

<u>Response</u>: The FDG cost in Year 1 is projected to be \$27,715 and in Year 2 it is projected to be \$38,755.

Very truly yours,

BUTLER SNOW LLP

Dan H. Elrod

clw Attachments

September 29, 2014 11:40am

AFFIDAVIT

TOTAL \$2,887,845

PROJECT COSTS CHART

		PROJECT COSTS CHART	September 29, 2014
Α,	Cons	struction and equipment acquired by purchase:	11:40am
	1.	Architectural and Engineering Fees	\$75,000
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$47,000
	3.	Acquisition of Site	: <u></u> Y
	4.	Preparation of Site	·
	5.	Construction Costs	\$460,000
	6.	Contingency Fund	<u>\$115,000</u>
	7.	Fixed Equipment (Not included in Construction Contract)	\$1,698,228
	8.	Moveable Equipment (List all equipment over \$50,000)	\$486,134 (no items over \$50,000)
	9.	Other (Specify)	
В.	Acqı	uisition by gift, donation, or lease:	
	1.	Facility (inclusive of building and land)	
	2.	Building only	
	3.	Land only	7
	4.	Equipment (Specify)	
	5.	Other (Specify)	
C.	Fina	incing Costs and Fees:	
	1.	Interim Financing	
	2.	Underwriting Costs	
	3.	Reserve for One Year's Debt Service	
	4.	Other (Specify)	
D.		mated Project Cost 3+C)	\$2,881,362
E.	CON	N Filing Fee	\$6,483
F.	Tota (D+	al Estimated Project Cost E)	\$2 887 845



STATE OF TENNESSEE Health Services and Dev Agency Office 31607001 9/29/2014 11:52 AM

Cashier:

annir0811001

Batch #:

684495

Trans #:

1 AE0710WD45

Workstation: A

AF0719WP45

CON Filing Fees 13158721

Receipt #: 131587 HA01 CON Filing Fees

\$449.00

Payment Total:

\$449.00

Transaction Total:

\$449.00

Check 21

\$449.00

Thank you for your payment. Have a nice day!

CN1409-041

